

**Pt. 447**

(b) *Subsequent termination.* The Medicaid agency must terminate a facility's provider agreement—

(1) Upon the agency's finding that the facility has been unable to achieve compliance with the conditions of participation for ICFs/IID during the period that payments for new admissions have been denied;

(2) Effective the day following the last day of the denial of payments period; and

(3) In accordance with the procedures for appeal of terminations set forth in subpart D of part 431 of this chapter.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

**Subparts D–F [Reserved]**

**PART 447—PAYMENTS FOR SERVICES**

**Subpart A—Payments: General Provisions**

Sec.

447.1 Purpose.

447.10 Prohibition against reassignment of provider claims.

447.15 Acceptance of State payment as payment in full.

447.20 Provider restrictions: State plan requirements.

447.21 Reduction of payments to providers.

447.25 Direct payments to certain beneficiaries for physicians' or dentists' services.

447.26 Prohibition on payment for provider-preventable conditions.

447.30 Withholding the Federal share of payments to Medicaid providers to recover Medicare overpayments.

447.31 Withholding Medicare payments to recover Medicaid overpayments.

447.40 Payments for reserving beds in institutions.

447.45 Timely claims payment.

447.46 Timely claims payment by MCOs.

**MEDICAID PREMIUMS AND COST SHARING**

447.50 Premiums and cost sharing: Basis and purpose.

447.51 Definitions.

447.52 Cost sharing.

447.53 Cost sharing for drugs.

447.54 Cost sharing for services furnished in a hospital emergency department.

447.55 Premiums.

447.56 Limitations on premiums and cost sharing.

447.57 Beneficiary and public notice requirements.

**42 CFR Ch. IV (10–1–15 Edition)**

447.88 Options for claiming FFP payment for section 1920A presumptive eligibility medical assistance payments.

447.90 FFP: Conditions related to pending investigations of credible allegations of fraud against the Medicaid program.

**Subpart B—Payment Methods: General Provisions**

447.200 Basis and purpose.

447.201 State plan requirements.

447.202 Audits.

447.203 Documentation of payment rates.

447.204 Encouragement of provider participation.

447.205 Public notice of changes in State-wide methods and standards for setting payment rates.

**Subpart C—Payment For Inpatient Hospital and Long-Term Care Facility Services**

447.250 Basis and purpose.

**PAYMENT RATES**

447.251 Definitions.

447.252 State plan requirements.

447.253 Other requirements.

447.255 Related information.

447.256 Procedures for CMS action on assurances and State plan amendments.

**FEDERAL FINANCIAL PARTICIPATION**

447.257 FFP: Conditions relating to institutional reimbursement.

**UPPER LIMITS**

447.271 Upper limits based on customary charges.

447.272 Inpatient services: Application of upper payment limits.

**SWING-BED HOSPITALS**

447.280 Hospital providers of NF services (swing-bed hospitals).

**Subpart D [Reserved]**

**Subpart E—Payment Adjustments for Hospitals That Serve a Disproportionate Number of Low-Income Patients**

447.294 Medicaid disproportionate share hospital (DSH) allotment reductions for Federal fiscal year 2014 and Federal fiscal year 2015.

447.295 Hospital-specific disproportionate share hospital payment limit: Determination of individuals without health insurance or other third party coverage.

447.296 Limitations on aggregate payments for disproportionate share hospitals for the period January 1, 1992 through September 30, 1992.

## Centers for Medicare & Medicaid Services, HHS

## § 447.10

447.297 Limitations on aggregate payments for disproportionate share hospitals beginning October 1, 1992.

447.298 State disproportionate share hospital allotments.

447.299 Reporting requirements.

### Subpart F—Payment Methods for Other Institutional and Noninstitutional Services

447.300 Basis and purpose.

447.302 State plan requirements.

447.304 Adherence to upper limits; FFP.

#### OUTPATIENT HOSPITAL AND CLINIC SERVICES

447.321 Outpatient hospital and clinic services: Application of upper payment limits.

#### OTHER INPATIENT AND OUTPATIENT FACILITIES

447.325 Other inpatient and outpatient facility services: Upper limits of payment.

447.342 [Reserved]

#### PREPAID CAPITATION PLANS

447.362 Upper limits of payment: Nonrisk contract.

#### RURAL HEALTH CLINIC SERVICES

447.371 Services furnished by rural health clinics.

### Subpart G—Payments for Primary Care Services Furnished by Physicians

447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.

447.405 Amount of required minimum payments.

447.410 State plan requirements.

447.415 Availability of Federal financial participation (FFP).

### Subpart H [Reserved]

### Subpart I—Payment for Drugs

447.500 Basis and purpose.

447.502 Definitions.

447.504 [Reserved]

447.505 Determination of best price.

447.506 Authorized generic drugs.

447.508 Exclusion from best price of certain sales at a nominal price.

447.510 Requirements for manufacturers.

447.512 Drugs: Aggregate upper limits of payment.

447.514 [Reserved]

447.516 Upper limits for drugs furnished as part of services.

447.518 State plan requirements, findings and assurances.

447.520 FFP: Conditions relating to physician-administered drugs.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted.

### Subpart A—Payments: General Provisions

#### § 447.1 Purpose.

This subpart prescribes State plan requirements, FFP limitations and procedures concerning payments made by State Medicaid agencies for Medicaid services.

#### § 447.10 Prohibition against reassignment of provider claims.

(a) *Basis and purpose.* This section implements section 1902(a)(32) of the Act which prohibits State payments for Medicaid services to anyone other than a provider or beneficiary, except in specified circumstances.

(b) *Definitions.* For purposes of this section:

*Facility* means an institution that furnishes health care services to inpatients.

*Factor* means an individual or an organization, such as a collection agency or service bureau, that advances money to a provider for accounts receivable that the provider has assigned, sold or transferred to the individual organization for an added fee or a deduction of a portion of the accounts receivable. Factor does not include a business representative as described in paragraph (f) of this section.

*Organized health care delivery system* means a public or private organization for delivering health services. It includes, but is not limited to, a clinic, a group practice prepaid capitation plan, and a health maintenance organization.

(c) *State plan requirements.* A State plan must provide that the requirements of paragraphs (d) through (h) of this section are met.

(d) *Who may receive payment.* Payment may be made only—

(1) To the provider; or

(2) To the beneficiary if he is a noncash beneficiary eligible to receive the payment under § 447.25; or

(3) In accordance with paragraphs (e), (f), and (g) of this section.

#### § 447.15

#### 42 CFR Ch. IV (10–1–15 Edition)

(e) *Reassignments.* Payment may be made in accordance with a reassignment from the provider to a government agency or reassignment by a court order.

(f) *Business agents.* Payment may be made to a business agent, such as a billing service or an accounting firm, that furnishes statements and receives payments in the name of the provider, if the agent's compensation for this service is—

(1) Related to the cost of processing the billing;

(2) Not related on a percentage or other basis to the amount that is billed or collected; and

(3) Not dependent upon the collection of the payment.

(g) *Individual practitioners.* Payment may be made to—

(1) The employer of the practitioner, if the practitioner is required as a condition of employment to turn over his fees to the employer;

(2) The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or

(3) A foundation, plan, or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

(4) In the case of a class of practitioners for which the Medicaid program is the primary source of service revenue, payment may be made to a third party on behalf of the individual practitioner for benefits such as health insurance, skills training and other benefits customary for employees.

(h) *Prohibition of payment to factors.* Payment for any service furnished to a beneficiary by a provider may not be made to or through a factor, either directly or by power of attorney.

[43 FR 45253, Sept. 29, 1978, as amended at 46 FR 42672, Aug. 24, 1981; 61 FR 38398, July 24, 1996; 79 FR 3039, Jan. 16, 2014]

#### § 447.15 Acceptance of State payment as payment in full.

A State plan must provide that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus

any deductible, coinsurance or copayment required by the plan to be paid by the individual. The provider may only deny services to any eligible individual on account of the individual's inability to pay the cost sharing amount imposed by the plan in accordance with § 447.52(e). The previous sentence does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the cost sharing charge.

[78 FR 42307, July 15, 2013]

#### § 447.20 Provider restrictions: State plan requirements.

A State plan must provide for the following:

(a) In the case of an individual who is eligible for medical assistance under the plan for service(s) for which a third party or parties is liable for payment, if the total amount of the established liability of the third party or parties for the service is—

(1) Equal to or greater than the amount payable under the State plan (which includes, when applicable, cost-sharing payments provided for in §§ 447.52 through 447.54), the provider furnishing the service to the individual may not seek to collect from the individual (or any financially responsible relative or representative of that individual) any payment amount for that service; or

(2) Less than the amount payable under the State plan (including cost sharing payments set forth in §§ 447.52 through 447.54), the provider furnishing the service to that individual may collect from the individual (or any financially responsible relative or representative of the individual) an amount which is the lesser of—

(i) Any cost-sharing payment amount imposed upon the individual under §§ 447.52 through 447.54; or

(ii) An amount which represents the difference between the amount payable under the State plan (which includes, where applicable, cost-sharing payments provided for in §§ 447.52 through 447.54) and the total of the established third party liability for the services.

(b) A provider may not refuse to furnish services covered under the plan to

an individual who is eligible for medical assistance under the plan on account of a third party's potential liability for the service(s).

[55 FR 1433, Jan. 16, 1990, as amended at 78 FR 42307, July 15, 2013]

**§ 447.21 Reduction of payments to providers.**

If a provider seeks to collect from an individual (or any financially responsible relative or representative of that individual) an amount that exceeds an amount specified under § 447.20(a)—

(a) The Medicaid agency may provide for a reduction of any payment amount otherwise due to the provider in addition to any other sanction available to the agency; and

(b) The reduction may be equal to up to three times the amount that the provider sought to collect in violation of § 447.20(a).

[55 FR 1433, Jan. 16, 1990]

**§ 447.25 Direct payments to certain beneficiaries for physicians' or dentists' services.**

(a) *Basis and purpose.* This section implements section 1905(a) of the Act by prescribing requirements applicable to States making direct payments to certain beneficiaries for physicians' or dentists' services.

(b) *State plan requirements.* Except for groups specified in paragraph (c) of this section, a State may make direct payments to beneficiaries for physicians' or dentists' services. If it does so, the State plan must—

(1) Provide for direct payments; and

(2) Specify the conditions under which payments are made.

(c) *Federal financial participation.* No FFP is available in expenditures for direct payment for physicians' or dentists' services to any beneficiary—

(1) Who is receiving assistance under the State's approved plan under title I, IV-A, X, XIV or XVI (AABD) of the Act; or

(2) To whom supplemental security benefits are being paid under title XVI of the Act; or

(3) Who is receiving or eligible for a State supplementary payment or would be eligible if he were not in a medical institution, and who is eligible for

Medicaid as a categorically needy beneficiary.

(d) *Federal requirements.* (1) Direct payments to beneficiaries under this section are an alternative to payments directly to providers and are subject to the same conditions; for example, the State's reasonable charge schedules are applicable.

(2) Direct payments must be supported by providers' bills for services.

**§ 447.26 Prohibition on payment for provider-preventable conditions.**

(a) *Basis and purpose.* The purpose of this section is to protect Medicaid beneficiaries and the Medicaid program by prohibiting payments by States for services related to provider-preventable conditions.

(1) Section 2702 of the Affordable Care Act requires that the Secretary exercise authority to prohibit Federal payment for certain provider preventable conditions (PPCs) and health care-acquired conditions (HCACs).

(2) Section 1902(a)(19) of the Act requires that States provide care and services consistent with the best interests of the beneficiaries.

(3) Section 1902(a)(30) of the Act requires that State payment methods must be consistent with efficiency, economy, and quality of care.

(b) *Definitions.* As used in this section—

*Health care-acquired condition* means a condition occurring in any inpatient hospital setting, identified as a HAC by the Secretary under section 1886(d)(4)(D)(iv) of the Act for purposes of the Medicare program identified in the State plan as described in section 1886(d)(4)(D)(ii) and (iv) of the Act; other than Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) as related to total knee replacement or hip replacement surgery in pediatric and obstetric patients.

*Other provider-preventable condition* means a condition occurring in any health care setting that meets the following criteria:

(i) Is identified in the State plan.

(ii) Has been found by the State, based upon a review of medical literature by qualified professionals, to be

#### § 447.30

reasonably preventable through the application of procedures supported by evidence-based guidelines.

(iii) Has a negative consequence for the beneficiary.

(iv) Is auditable.

(v) Includes, at a minimum, wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part; surgical or other invasive procedure performed on the wrong patient.

*Provider-preventable condition* means a condition that meets the definition of a “health care-acquired condition” or an “other provider-preventable condition” as defined in this section.

(c) *General rules.* (1) A State plan must provide that no medical assistance will be paid for “provider-preventable conditions” as defined in this section; and as applicable for individuals dually eligible for both the Medicare and Medicaid programs.

(2) No reduction in payment for a provider preventable condition will be imposed on a provider when the condition defined as a PPC for a particular patient existed prior to the initiation of treatment for that patient by that provider.

(3) Reductions in provider payment may be limited to the extent that the following apply:

(i) The identified provider-preventable conditions would otherwise result in an increase in payment.

(ii) The State can reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the provider-preventable conditions.

(4) FFP will not be available for any State expenditure for provider-preventable conditions.

(5) A State plan must ensure that non-payment for provider-preventable conditions does not prevent access to services for Medicaid beneficiaries.

(d) *Reporting.* State plans must require that providers identify provider-preventable conditions that are associated with claims for Medicaid payment or with courses of treatment furnished to Medicaid patients for which Medicaid payment would otherwise be available.

[76 FR 32837, June 6, 2011]

#### 42 CFR Ch. IV (10–1–15 Edition)

#### § 447.30 Withholding the Federal share of payments to Medicaid providers to recover Medicare overpayments.

(a) *Basis and purpose.* This section implements section 1914 of the Act, which provides for withholding the Federal share of Medicaid payments to a provider if the provider has not arranged to repay Medicare overpayments or has failed to provide information to determine the amount of the overpayments. The intent of the statute and regulations is to facilitate the recovery of Medicare overpayments. The provision enables recovery of overpayments when institutions have reduced participation in Medicare or when physicians and suppliers have submitted few or no claims under Medicare, thus not receiving enough in Medicare reimbursement to permit offset of the overpayment.

(b) *When withholding occurs.* The Federal share of Medicaid payments may be withheld from any provider specified in paragraph (c) of this section to recover Medicare overpayments that CMS has been unable to collect if the provider participates in Medicaid and—

(1) The provider has not made arrangements satisfactory to CMS to repay the Medicare overpayment; or

(2) CMS has been unable to collect information from the provider to determine the existence or amount of Medicare overpayment.

(c) The Federal share of Medicaid payments may be withheld with respect to the following providers:

(1) An institutional provider that has or previously had in effect a Medicare provider agreement under section 1866 of the Act; and

(2) A Medicaid provider who has previously accepted Medicare payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act; and during the 12 month period preceding the quarter in which the Federal share is to be withheld for a Medicare overpayment, submitted no claims under Medicare or submitted claims which total less than the amount of overpayment.

(d) *Order to reduce State payment.* (1) CMS may, at its discretion, issue an order to the Medicaid agency of any

State that is using the provider's services, to reduce its payment to the provider by the amount specified in paragraph (f) of this section.

(2) The order to reduce payment to the provider will remain in effect until—

(i) The Medicaid agency determines that the overpayment has been completely recovered; or

(ii) CMS terminates the order.

(3) CMS may withhold FFP from any State that does not comply with the order specified in paragraph (d)(1) of this section to reduce payment to the provider and claims FFP for the expenditure on its quarterly expenditure report.

(e) *Notice of withholding.* (1) Before the Federal share of payments may be withheld under this section, CMS will notify the provider and the Medicaid agency of each State that CMS believes may use the overpaid provider's services under Medicaid.

(2) The notice will include the instruction to reduce State payments, as provided under paragraph (d) of this section.

(3) CMS will send the notice referred to in paragraph (e)(1) by certified mail, return receipt requested.

(4) Each Medicaid agency must identify the amount of payment due the provider under Medicaid and give that information to CMS in the next quarterly expenditure report.

(5) The Medicaid agency may appeal any disallowance of FFP resulting from the withholding decision to the Grant Appeals Board, in accordance with 45 CFR part 16.

(f) Amount to be withheld. CMS may require the Medicaid agency to reduce the Federal share of its payment to the provider by the lesser of the following amounts.

(1) The Federal matching share of payments to the provider, or

(2) The total Medicare overpayment to the provider.

(g) *Effective date of withholding.* Withholding of payment will become effective no less than 60 days after the day on which the agency receives notice of withholding.

(h) *Duration of withholding.* No Federal funds are available in expenditures for services that are furnished by a pro-

vider specified in paragraph (c) of this section from the date on which the withholding becomes effective until the termination of withholding under paragraph (i) of this section.

(i) *Termination of withholding.* (1) CMS will terminate the order to reduce State payment if it determines that any of the following has occurred:

(i) The Medicare overpayment is completely recovered;

(ii) The institution or person makes an agreement satisfactory to CMS to repay the overpayment; or

(iii) CMS determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(2) CMS will notify each State that previously received a notice ordering the withholding that the withholding has been terminated.

(j) *Procedures for restoring excess withholding.* If an amount ultimately determined to be in excess of the Medicare overpayment is withheld, CMS will restore any excess funds withheld.

(k) *Recovery of funds from Medicaid agency.* A provider is not entitled to recover from the Medicaid agency the amount of payment withheld by the agency in accordance with a CMS order issued under paragraph (d) of this section.

[50 FR 19688, May 10, 1985; 50 FR 23307, June 3, 1985]

#### **§ 447.31 Withholding Medicare payments to recover Medicaid overpayments.**

(a) *Basis and purpose.* Section 1885 of the Act provides authority for CMS to withhold Medicare payments to a Medicaid provider in order to recover Medicaid overpayments to the provider. Section 405.377 of this chapter sets forth the Medicare rules implementing section 1885, and specifies under what circumstances withholding will occur and the providers that are subject to withholding. This section establishes the procedures that the Medicaid agency must follow when requesting that CMS withhold Medicare payments.

(b) *Agency notice to providers.* (1) Before the agency requests recovery of a Medicaid overpayment through Medicare, the agency must send either or

#### § 447.40

#### 42 CFR Ch. IV (10–1–15 Edition)

both of the following notices, in addition to that required under paragraph (b)(2) of this section, to the provider.

(i) Notice that—

(A) There has been an overpayment;

(B) Repayment is required; and

(C) The overpayment determination is subject to agency appeal procedures, but we may withhold Medicare payments while an appeal is in progress.

(ii) Notice that—

(A) Information is needed to determine the amount of overpayment if any; and

(B) The provider has at least 30 days in which to supply the information to the agency.

(2) Notice that, 30 days or later from the date of the notice, the agency intends to refer the case to CMS for withholding of Medicare payments.

(3) The agency must send all notices to providers by certified mail, return receipt requested.

(c) *Documentation to be submitted to CMS.* The agency must submit the following information or documentation to CMS (unless otherwise specified) with the request for withholding of Medicare payments.

(1) A statement of the reason that withholding is requested.

(2) The amount of overpayment, type of overpayment, date the overpayment was determined, and the closing date of the pertinent cost reporting period (if applicable).

(3) The quarter in which the overpayment was reported on the quarterly expenditure report (Form CMS 64).

(4) As needed, and upon request from CMS, the names and addresses of the provider's officers and owners for each period that there is an outstanding overpayment.

(5) A statement of assurance that the State agency has met the notice requirements under paragraph (b) of this section.

(6) As needed, and upon request for CMS, copies of notices (under paragraph (b) of this section), and reports of contact or attempted contact with the provider concerning the overpayment, including any reduction or suspension of Medicaid payments made with respect to that overpayment.

(7) A copy of the provider's agreement with the agency under § 431.107 of this chapter.

(d) *Notification to terminate withholding.* (1) If an agency has requested withholding under this section, it must notify CMS if any of the following occurs:

(i) The Medicaid provider makes an agreement satisfactory to the agency to repay the overpayment;

(ii) The Medicaid overpayment is completely recovered; or

(iii) The agency determines that there is no overpayment, based on newly acquired evidence or subsequent audit.

(2) Upon receipt of notification from the State agency, CMS will terminate withholding.

(e) *Accounting for returned overpayment.* The agency must treat as a recovered overpayment the amounts received from CMS to offset Medicaid overpayments.

(f) *Procedures for restoring excess withholding.* The agency must establish procedures satisfactory to CMS to assure the return to the provider of amounts withheld under this section that are ultimately determined to be in excess of overpayments. Those procedures are subject to CMS review.

[50 FR 19689, May 10, 1985, as amended at 61 FR 63749, Dec. 2, 1996]

#### § 447.40 Payments for reserving beds in institutions.

(a) The Medicaid agency may make payments to reserve a bed during a beneficiary's temporary absence from an inpatient facility, if—

(1) The State plan provides for such payments and specifies any limitations on the policy; and

(2) Absences for purposes other than required hospitalization (which cannot be anticipated and planned) are included in the patient's plan of care.

(b) An agency that pays for reserved beds in an inpatient facility may pay less for a reserved bed than an occupied bed if there is a cost differential between the two beds. (Section 1102 of the Act.)

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986]

**§ 447.45 Timely claims payment.**

(a) *Basis and purpose.* This section implements section 1902(a)(37) of the Act by specifying—

(1) State plan requirements for—

(i) Timely processing of claims for payment;

(ii) Prepayment and postpayment claims reviews; and

(2) Conditions under which the Administrator may grant waivers of the time requirements.

(b) *Definitions.* *Claim* means (1) a bill for services, (2) a line item of service, or (3) all services for one beneficiary within a bill.

*Clean claim* means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a State's claims system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

A *shared health facility* means any arrangement in which—

(1) Two or more health care practitioners practice their professions at a common physical location;

(2) The practitioners share common waiting areas, examining rooms, treatment rooms, or other space, the services of supporting staff, or equipment;

(3) The practitioners have a person (who may himself be a practitioner)—

(i) Who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at the common physical location other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) Who makes available to the practitioners the services of supporting staff who are not employees of the practitioners; and

(iii) Who is compensated in whole or in part, for the use of the common physical location or related support services, on a basis related to amounts charged or collected for the services rendered or ordered at the location or on any basis clearly unrelated to the value of the services provided by the person; and

(4) At least one of the practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding \$5,000 for any one month during the preceding 12 months or in an aggregate amount exceeding \$40,000 during the preceding 12 months.

The term does not include a provider of services (as specified in § 489.2(b) of this chapter), a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.

*Third party* is defined in § 433.135 of this chapter.

(c) *State plan requirements.* A State plan must (1) provide that the requirements of paragraphs (d), (e)(2), (f) and (g) of this section are met; and

(2) Specify the definition of a claim, as provided in paragraph (b) of this section, to be used in meeting the requirements for timely claims payment. The definition may vary by type of service (e.g., physician service, hospital service).

(d) *Timely processing of claims.* (1) The Medicaid agency must require providers to submit all claims no later than 12 months from the date of service.

(2) The agency must pay 90 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 30 days of the date of receipt.

(3) The agency must pay 99 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 90 days of the date of receipt.

(4) The agency must pay all other claims within 12 months of the date of receipt, except in the following circumstances:

(i) This time limitation does not apply to retroactive adjustments paid to providers who are reimbursed under a retrospective payment system, as defined in § 447.272 of this part.

(ii) If a claim for payment under Medicare has been filed in a timely



#### § 447.46

manner, the agency may pay a Medicaid claim relating to the same services within 6 months after the agency or the provider receives notice of the disposition of the Medicare claim.

(iii) The time limitation does not apply to claims from providers under investigation for fraud or abuse.

(iv) The agency may make payments at any time in accordance with a court order, to carry out hearing decisions or agency corrective actions taken to resolve a dispute, or to extend the benefits of a hearing decision, corrective action, or court order to others in the same situation as those directly affected by it.

(5) The date of receipt is the date the agency receives the claim, as indicated by its date stamp on the claim.

(6) The date of payment is the date of the check or other form of payment.

(e) *Waivers.* (1) The Administrator may waive the requirements of paragraphs (d) (2) and (3) of this section upon request by an agency if he finds that the agency has shown good faith in trying to meet them. In deciding whether the agency has shown good faith, the Administrator will consider whether the agency has received an unusually high volume of claims which are not clean claims, and whether the agency is making diligent efforts to implement an automated claims processing and information retrieval system.

(2) The agency's request for a waiver must contain a written plan of correction specifying all steps it will take to meet the requirements of this section.

(3) The Administrator will review each case and if he approves a waiver, will specify its expiration date, based on the State's capability and efforts to meet the requirements of this section.

(f) *Prepayment and postpayment claims review.* (1) For all claims, the agency must conduct prepayment claims review consisting of—

(i) Verification that the beneficiary was included in the eligibility file and that the provider was authorized to furnish the service at the time the service was furnished;

(ii) Checks that the number of visits and services delivered are logically consistent with the beneficiary's characteristics and circumstances, such as

#### 42 CFR Ch. IV (10–1–15 Edition)

type of illness, age, sex, service location;

(iii) Verification that the claim does not duplicate or conflict with one reviewed previously or currently being reviewed;

(iv) Verification that a payment does not exceed any reimbursement rates or limits in the State plan; and

(v) Checks for third party liability within the requirements of § 433.137 of this chapter.

(2) The agency must conduct post-payment claims review that meets the requirements of parts 455 and 456 of this chapter, dealing with fraud and utilization control.

(g) *Reports.* The agency must provide any reports and documentation on compliance with this section that the Administrator may require.

(Secs. 1102 and 1902(a)(37) of the Social Security Act (42 U.S.C. 1302, 1396a(a)(37)))

[44 FR 30344, May 25, 1979, as amended at 55 FR 1434, Jan. 16, 1990]

#### § 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* “Claim” and “clean claim” have the meaning given those terms in § 447.45.

(c) *Contract requirements—*(1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of § 447.45(d)(2) and (d)(3), and abide by the specifications of § 447.45(d)(5) and (d)(6).

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) *Alternative schedule.* Any alternative schedule must be stipulated in the contract.

[67 FR 41115, June 14, 2002]

#### MEDICAID PREMIUMS AND COST SHARING

SOURCE: 78 FR 42307, July 15, 2013, unless otherwise noted.

**§ 447.50 Premiums and cost sharing: Basis and purpose.**

Sections 1902(a)(14), 1916 and 1916A of the Act permit states to require certain beneficiaries to share in the costs of providing medical assistance through premiums and cost sharing. Sections 447.52 through 447.56 specify the standards and conditions under which states may impose such premiums and or cost sharing.

**§ 447.51 Definitions.**

As used in this part—

*Alternative non-emergency services provider* means a Medicaid provider, such as a physician's office, health care clinic, community health center, hospital outpatient department, or similar provider that can provide clinically appropriate services in a timely manner.

*Contract health service* means any health service that is:

(1) Delivered based on a referral by, or at the expense of, an Indian health program; and

(2) Provided by a public or private medical provider or hospital that is not a provider or hospital of the IHS or any other Indian health program

*Cost sharing* means any copayment, coinsurance, deductible, or other similar charge.

*Emergency services* has the same meaning as in § 438.114 of this chapter.

*Federal poverty level (FPL)* means the Federal poverty level updated periodically in the FEDERAL REGISTER by the Secretary of Health and Human Services under the authority of 42 U.S.C. 9902(2).

*Indian* means any individual defined at 25 U.S.C. 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(1) Is a member of a Federally-recognized Indian tribe;

(2) Resides in an urban center and meets one or more of the following four criteria:

(i) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(ii) Is an Eskimo or Aleut or other Alaska Native;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(iv) Is determined to be an Indian under regulations promulgated by the Secretary;

(3) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(4) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

*Indian health care provider* means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

*Inpatient stay* means the services received during a continuous period of inpatient days in either a single medical institution or multiple medical institutions, and also includes a return to an inpatient medical institution after a brief period when the return is for treatment of a condition that was present in the initial period. Inpatient has the same meaning as in § 440.2 of this chapter.

*Non-emergency services* means any care or services that are not considered emergency services as defined in this section. This does not include any services furnished in a hospital emergency department that are required to be provided as an appropriate medical screening examination or stabilizing examination and treatment under section 1867 of the Act.

*Outpatient services* for purposes of imposing cost sharing means any service or supply not meeting the definition of an inpatient stay.

*Preferred drugs* means drugs that the state has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost effective drugs within each therapeutically equivalent or therapeutically similar class of drugs, or all drugs

## § 447.52

## 42 CFR Ch. IV (10–1–15 Edition)

within such a class if the agency does not differentiate between preferred and non-preferred drugs.

*Premium* means any enrollment fee, premium, or other similar charge.

### § 447.52 Cost sharing.

(a) *Applicability.* Except as provided in § 447.56(a) (exemptions), the agency may impose cost sharing for any service under the state plan.

(b) *Maximum Allowable Cost Sharing.*

(1) At State option, cost sharing imposed for any service (other than for drugs and non-emergency services fur-

nished in an emergency department, as described in §§ 447.53 and 447.54 respectively) may be established at or below the amounts shown in the following table (except that the maximum allowable cost sharing for individuals with family income at or below 100 percent of the FPL shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI-U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment):

Services	Maximum allowable cost sharing		
	Individuals with family income ≤100% of the FPL	Individuals with family income 101–150% of the FPL	Individuals with family income >150% of the FPL
Outpatient Services ( <i>physician visit, physical therapy, etc.</i> ).	\$4	10% of cost the agency pays .....	20% of cost the agency pays.
Inpatient Stay .....	75	10% of total cost the agency pays for the entire stay.	20% of total cost the agency pays for the entire stay.

(2) States with cost sharing for an inpatient stay that exceeds \$75, as of July 15, 2013, must submit a plan to CMS that provides for reducing inpatient cost sharing to \$75 on or before July 1, 2017.

(3) In states that do not have fee-for-service payment rates, any cost sharing imposed on individuals at any income level may not exceed the maximum amount established, for individuals with income at or below 100 percent of the FPL described in paragraph (b)(1) of this section.

(c) *Maximum cost sharing.* In no case shall the maximum cost sharing established by the agency be equal to or exceed the amount the agency pays for the service.

(d) *Targeted cost sharing.* (1) Except as provided in paragraph (d)(2) of this section, the agency may target cost sharing to specified groups of individuals with family income above 100 percent of the FPL.

(2) For cost sharing imposed for non-preferred drugs under § 447.53 and for non-emergency services provided in a hospital emergency department under § 447.54, the agency may target cost sharing to specified groups of individuals regardless of income.

(e) *Denial of service for nonpayment.* (1) The agency may permit a provider,

including a pharmacy or hospital, to require an individual to pay cost sharing as a condition for receiving the item or service if—

(i) The individual has family income above 100 percent of the FPL,

(ii) The individual is not part of an exempted group under § 447.56(a), and

(iii) For cost sharing imposed for non-emergency services furnished in an emergency department, the conditions under § 447.54(d) of this part have been satisfied.

(2) Except as provided under paragraph (e)(1) of this section, the state plan must specify that no provider may deny services to an eligible individual on account of the individual's inability to pay the cost sharing.

(3) Nothing in this section shall be construed as prohibiting a provider from choosing to reduce or waive such cost sharing on a case-by-case basis.

(f) *Prohibition against multiple charges.* For any service, the agency may not impose more than one type of cost sharing.

(g) *Income-related charges.* Subject to the maximum allowable charges specified in §§ 447.52(b), 447.53(b) and 447.54(b), the plan may establish different cost sharing charges for individuals at different income levels. If the agency imposes such income-related

## Centers for Medicare &amp; Medicaid Services, HHS

## § 447.53

charges, it must ensure that lower income individuals are charged less than individuals with higher income.

(h) *Services furnished by a managed care organization (MCO).* Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the cost sharing specified in the state plan and the requirements set forth in §§ 447.50 through 447.57.

(i) *State Plan Specifications.* For each cost sharing charge imposed under this part, the state plan must specify—

(1) The service for which the charge is made;

(2) The group or groups of individuals that may be subject to the charge;

(3) The amount of the charge;

(4) The process used by the state to—

(i) Ensure individuals exempt from cost sharing are not charged,

(ii) Identify for providers whether cost sharing for a specific item or service may be imposed on an individual and whether the provider may require the individual, as a condition for receiving the item or service, to pay the cost sharing charge; and

(5) If the agency imposes cost sharing under § 447.54, the process by which hos-

pital emergency room services are identified as non-emergency service.

#### § 447.53 Cost sharing for drugs.

(a) The agency may establish differential cost sharing for preferred and non-preferred drugs. The provisions in § 447.56(a) shall apply except as the agency exercises the option under paragraph (d) of this section. All drugs will be considered preferred drugs if so identified or if the agency does not differentiate between preferred and non-preferred drugs.

(b) At state option, cost sharing for drugs may be established at or below the amounts shown in the following table (except that the maximum allowable cost sharing shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI-U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment. Such increase shall not be applied to any cost sharing that is based on the amount the agency pays for the service):

Services	Maximum allowable cost sharing	
	Individuals with family income ≤150% of the FPL	Individuals with family income >150% of the FPL
Preferred Drugs .....	\$4	\$4.
Non-Preferred Drugs .....	8	20% of the cost the agency pays.

(c) In states that do not have fee-for-service payment rates, cost sharing for prescription drugs imposed on individuals at any income level may not exceed the maximum amount established for individuals with income at or below 150 percent of the FPL in paragraph (b) of this section.

(d) For individuals otherwise exempt from cost sharing under § 447.56(a), the agency may impose cost sharing for non-preferred drugs, not to exceed the maximum amount established in paragraph (b) of this section.

(e) In the case of a drug that is identified by the agency as a non-preferred drug within a therapeutically equivalent or therapeutically similar class of drugs, the agency must have a timely

process in place so that cost sharing is limited to the amount imposed for a preferred drug if the individual's prescribing provider determines that a preferred drug for treatment of the same condition either will be less effective for the individual, will have adverse effects for the individual, or both. In such cases the agency must ensure that reimbursement to the pharmacy is based on the appropriate cost sharing amount.

**§ 447.54**

**42 CFR Ch. IV (10–1–15 Edition)**

**§ 447.54 Cost sharing for services furnished in a hospital emergency department.**

(a) The agency may impose cost sharing for non-emergency services provided in a hospital emergency department. The provisions in § 447.56(a) shall apply except as the agency exercises the option under paragraph (c) of this section.

(b) At state option, cost sharing for non-emergency services provided in an emergency department may be estab-

lished at or below the amounts shown in the following table (except that the maximum allowable cost sharing identified for individuals with family income at or below 150 percent of the FPL shall be increased each year, beginning October 1, 2015, by the percentage increase in the medical care component of the CPI-U for the period of September to September of the preceding calendar year, rounded to the next higher 5-cent increment):

Services	Maximum allowable cost sharing	
	Individuals with family income ≤150% of the FPL	Individuals with family income >150% of the FPL
Non-emergency Use of the Emergency Department .....	\$8 .....	No Limit.

(c) For individuals otherwise exempt from cost sharing under § 447.56(a), the agency may impose cost sharing for non-emergency use of the emergency department, not to exceed the maximum amount established in paragraph (b) of this section for individuals with income at or below 150 percent of the FPL.

(d) For the agency to impose cost sharing under paragraph (a) or (c) of this section for non-emergency use of the emergency department, the hospital providing the care must—

(1) Conduct an appropriate medical screening under § 489.24 subpart G to determine that the individual does not need emergency services.

(2) Before providing non-emergency services and imposing cost sharing for such services:

(i) Inform the individual of the amount of his or her cost sharing obligation for non-emergency services provided in the emergency department;

(ii) Provide the individual with the name and location of an available and accessible alternative non-emergency services provider;

(iii) Determine that the alternative provider can provide services to the individual in a timely manner with the imposition of a lesser cost sharing amount or no cost sharing if the individual is otherwise exempt from cost sharing; and

(iv) Provide a referral to coordinate scheduling for treatment by the alternative provider.

(e) Nothing in this section shall be construed to:

(1) Limit a hospital's obligations for screening and stabilizing treatment of an emergency medical condition under section 1867 of the Act; or

(2) Modify any obligations under either state or federal standards relating to the application of a prudent-layperson standard for payment or coverage of emergency medical services by any managed care organization.

**§ 447.55 Premiums.**

(a) The agency may impose premiums upon individuals whose income exceeds 150 percent of the FPL, subject to the exemptions set forth in § 447.56(a) and the aggregate limitations set forth in § 447.56(f) of this part, except that:

(1) Pregnant women described in described in paragraph (a)(1)(ii) of this section may be charged premiums that do not exceed 10 percent of the amount by which their family income exceeds 150 percent of the FPL after deducting expenses for care of a dependent child.

(i) The agency may use state or local funds available under other programs for payment of a premium for such pregnant women. Such funds shall not be counted as income to the individual for whom such payment is made.

(ii) Pregnant women described in this clause include pregnant women eligible for Medicaid under § 435.116 of this chapter whose income exceeds the higher of –

(A) 150 percent FPL; and

(B) If applicable, the percent FPL described in section 1902(l)(2)(A)(iv) of the Act up to 185 percent FPL.

(2) Individuals provided medical assistance only under sections 1902(a)(10)(A)(ii)(XV) or 1902(a)(10)(A)(ii)(XVI) of the Act and the Ticket to Work and Work Incentives Improvement Act of 1999 (TWWIIA), may be charged premiums on a sliding scale based on income.

(3) Disabled children provided medical assistance under section 1902(a)(10)(A)(ii)(XIX) of the Act in accordance with the Family Opportunity Act, may be charged premiums on a sliding scale based on income. The aggregate amount of the child's premium imposed under this paragraph and any premium that the parent is required to pay for family coverage under section 1902(cc)(2)(A)(i) of the Act, and other cost sharing charges may not exceed:

(i) 5 percent of the family's income if the family's income is no more than 200 percent of the FPL.

(ii) 7.5 percent of the family's income if the family's income exceeds 200 percent of the FPL but does not exceed 300 percent of the FPL.

(4) Qualified disabled and working individuals described in section 1905(s) of the Act, whose income exceeds 150 percent of the FPL, may be charged premiums on a sliding scale based on income, expressed as a percentage of Medicare cost sharing described at section 1905(p)(3)(A)(i) of the Act.

(5) Medically needy individuals, as defined in §§ 435.4 and 436.3 of this chapter, may be charged on a sliding scale. The agency must impose an appropriately higher charge for each higher level of family income, not to exceed \$20 per month for the highest level of family income.

(b) *Consequences for non-payment.* (1) For premiums imposed under paragraphs (a)(1), (a)(2), (a)(3) and (a)(4) of this section, the agency may not require a group or groups of individuals to prepay.

(2) Except for premiums imposed under paragraph (a)(5) of this section, the agency may terminate an individual from medical assistance on the basis of failure to pay for 60 days or more.

(3) For premiums imposed under paragraph (a)(2) of this section—

(i) For individuals with annual income exceeding 250 percent of the FPL, the agency may require payment of 100 percent of the premiums imposed under this paragraph for a year, such that payment is only required up to 7.5 percent of annual income for individuals whose annual income does not exceed 450 percent of the FPL.

(ii) For individuals whose annual adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986) exceeds \$75,000, increased by inflation each calendar year after 2000, the agency must require payment of 100 percent of the premiums for a year, except that the agency may choose to subsidize the premiums using state funds which may not be federally matched by Medicaid.

(4) For any premiums imposed under this section, the agency may waive payment of a premium in any case where the agency determines that requiring the payment will create an undue hardship for the individual or family.

(5) The agency may not apply further consequences or penalties for non-payment other than those listed in this section.

(c) *State plan specifications.* For each premium, enrollment fee, or similar charge imposed under paragraph (a) of this section, subject to the requirements of paragraph (b) of this section, the plan must specify—

(1) The group or groups of individuals that may be subject to the charge;

(2) The amount and frequency of the charge;

(3) The process used by the state to identify which beneficiaries are subject to premiums and to ensure individuals exempt from premiums are not charged; and

(4) The consequences for an individual or family who does not pay.

**§ 447.56 Limitations on premiums and cost sharing.**

(a) *Exemptions.* (1) The agency may not impose premiums or cost sharing upon the following groups of individuals:

(i) Individuals ages 1 and older and under age 18 eligible under § 435.118 of this chapter.

(ii) Infants under age 1 eligible under § 435.118 of this chapter whose income does not exceed the higher of—

(A) 150 percent FPL (for premiums) or 133 percent FPL (for cost sharing); and

(B) If applicable, the percent FPL described in section 1902(l)(2)(A)(iv) of the Act up to 185 percent FPL.

(iii) Individuals under age 18 eligible under §§ 435.120–435.122 or § 435.130 of this chapter.

(iv) Children for whom child welfare services are made available under Part B of title IV of the Act on the basis of being a child in foster care and individuals receiving benefits under Part E of that title, without regard to age.

(v) At state option, individuals under age 19, 20 or age 21, eligible under § 435.222 of this chapter.

(vi) Disabled children, except as provided at § 447.55(a)(4) (premiums), who are receiving medical assistance by virtue of the application of the Family Opportunity Act in accordance with sections 1902(a)(10)(A)(ii)(XIX) and 1902(cc) of the Act.

(vii) Pregnant women, except for premiums allowed under § 447.55(a)(1) and cost sharing for services specified in the state plan as not pregnancy-related, during the pregnancy and through the postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.

(viii) Any individual whose medical assistance for services furnished in an institution, or at state option in a home and community-based setting, is reduced by amounts reflecting available income other than required for personal needs.

(ix) An individual receiving hospice care, as defined in section 1905(o) of the Act.

(x) An Indian who is eligible to receive or has received an item or service

furnished by an Indian health care provider or through referral under contract health services is exempt from premiums. Indians who are currently receiving or have ever received an item or service furnished by an Indian health care provider or through referral under contract health services are exempt from all cost sharing.

(xi) Individuals who are receiving Medicaid because of the state's election to extend coverage as authorized by § 435.213 of this chapter (Breast and Cervical Cancer).

(2) The agency may not impose cost sharing for the following services:

(i) Emergency services as defined at section 1932(b)(2) of the Act and § 438.114(a) of this chapter;

(ii) Family planning services and supplies described in section 1905(a)(4)(C) of the Act, including contraceptives and pharmaceuticals for which the State claims or could claim Federal match at the enhanced rate under section 1903(a)(5) of the Act for family planning services and supplies;

(iii) Preventive services, at a minimum the services specified at § 457.520 of chapter D, provided to children under 18 years of age regardless of family income, which reflect the well-baby and well child care and immunizations in the Bright Futures guidelines issued by the American Academy of Pediatrics; and

(iv) Pregnancy-related services, including those defined at §§ 440.210(a)(2) and 440.250(p) of this chapter, and counseling and drugs for cessation of tobacco use. All services provided to pregnant women will be considered as pregnancy-related, except those services specifically identified in the state plan as not being related to the pregnancy.

(v) Provider-preventable services as defined in § 447.26(b).

(b) *Applicability.* Except as permitted under § 447.52(d) (targeted cost sharing), the agency may not exempt additional individuals from cost sharing obligations that apply generally to the population at issue.

(c) *Payments to providers.* (1) Except as provided under paragraphs (c)(2) and (c)(3) of this section, the agency must reduce the payment it makes to a provider by the amount of a beneficiary's cost sharing obligation, regardless of

whether the provider has collected the payment or waived the cost sharing.

(2) For items and services provided to Indians who are exempt from cost sharing under paragraph (a)(1)(x) of this section, the agency may not reduce the payment it makes to a provider, including an Indian health care provider, by the amount of cost sharing that will otherwise be due from the Indian.

(3) For those providers that the agency reimburses under Medicare reasonable cost reimbursement principles, in accordance with subpart B of this part, an agency may increase its payment to offset uncollected cost sharing charges that are bad debts of providers.

(d) *Payments to managed care organizations.* If the agency contracts with a managed care organization, the agency must calculate its payments to the organization to include cost sharing established under the state plan, for beneficiaries not exempt from cost sharing under paragraph (a) of this section, regardless of whether the organization imposes the cost sharing on its recipient members or the cost sharing is collected.

(e) *Payments to states.* No FFP in the state's expenditures for services is available for—

(1) Any premiums or cost sharing amounts that recipients should have paid under §§ 447.52 through 447.55 (except for amounts that the agency pays as bad debts of providers under paragraph (c)(3) of this section; and

(2) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium, except for amounts for premium assistance to obtain coverage for eligible individuals through family coverage that may include ineligible individuals when authorized in the approved state plan.

(f) *Aggregate limits.* (1) Medicaid premiums and cost sharing incurred by all individuals in the Medicaid household may not exceed an aggregate limit of 5 percent of the family's income applied on either a quarterly or monthly basis, as specified by the agency.

(2) If the state adopts premiums or cost sharing rules that could place beneficiaries at risk of reaching the aggregate family limit, the state plan must indicate a process to track each

family's incurred premiums and cost sharing through an effective mechanism that does not rely on beneficiary documentation.

(3) The agency must inform beneficiaries and providers of the beneficiaries aggregate limit and notify beneficiaries and providers when a beneficiary has incurred out-of-pocket expenses up to the aggregate family limit and individual family members are no longer subject to cost sharing for the remainder of the family's current monthly or quarterly cap period.

(4) The agency must have a process in place for beneficiaries to request a reassessment of their family aggregate limit if they have a change in circumstances or if they are being terminated for failure to pay a premium.

(5) Nothing in paragraph (f) shall preclude the agency from establishing additional aggregate limits, including but not limited to a monthly limit on cost sharing charges for a particular service.

**§ 447.57 Beneficiary and public notice requirements.**

(a) The agency must make available a public schedule describing current premiums and cost sharing requirements containing the following information:

(1) The group or groups of individuals who are subject to premiums and/or cost sharing and the current amounts;

(2) Mechanisms for making payments for required premiums and cost sharing charges;

(3) The consequences for an applicant or recipient who does not pay a premium or cost sharing charge;

(4) A list of hospitals charging cost sharing for non-emergency use of the emergency department; and

(5) A list of preferred drugs or a mechanism to access such a list, including the agency Web site.

(b) The agency must make the public schedule available to the following in a manner that ensures that affected applicants, beneficiaries, and providers are likely to have access to the notice:

(1) Beneficiaries, at the time of their enrollment and reenrollment after a redetermination of eligibility, and when premiums, cost sharing charges, or aggregate limits are revised, notice



## § 447.88

## 42 CFR Ch. IV (10–1–15 Edition)

to beneficiaries must be in accordance with § 435.905(b) of this chapter;

(2) Applicants, at the time of application;

(3) All participating providers; and

(4) The general public.

(c) Prior to submitting to the Centers for Medicare & Medicaid Services for approval a state plan amendment (SPA) to establish or substantially modify existing premiums or cost sharing, or change the consequences for non-payment, the agency must provide the public with advance notice of the SPA, specifying the amount of premiums or cost sharing and who is subject to the charges. The agency must provide a reasonable opportunity to comment on such SPAs. The agency must submit documentation with the SPA to demonstrate that these requirements were met. If premiums or cost sharing is substantially modified during the SPA approval process, the agency must provide additional public notice.

### § 447.88 Options for claiming FFP payment for section 1920A presumptive eligibility medical assistance payments.

(a) The FMAP rate for medical assistance payments made available to a child during a presumptive eligibility period under section 1920A of the Act is the regular FMAP under title XIX, based on the category of medical assistance; that is, the enhanced FMAP is not available for section 1920A presumptive eligibility expenditures.

(b) States have the following 3 options for identifying Medicaid section 1920A presumptive eligibility expenditures and the application of payments for those expenditures:

(1) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended with no further adjustment based on the results of a subsequent actual eligibility determination (if any).

(2) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended but may adjust reported expenditures based on results of the actual eligibility determination (if any) to reflect the actual eligibility status of the indi-

vidual, if other than presumptively eligible.

(3) A State may elect to delay submission of claims for payments of section 1920A presumptive eligibility expenditures until after the actual eligibility determination (if any) is made and, at that time identify such expenditures based on the actual eligibility status of individuals if other than presumptively eligible. At that time, the State would, as appropriate, recategorize the medical assistance expenditures made during the section 1920A presumptive eligibility period based on the results of the actual eligibility determination, and claim them appropriately.

[65 FR 33622, May 24, 2000]

### § 447.90 FFP: Conditions related to pending investigations of credible allegations of fraud against the Medicaid program.

(a) *Basis and purpose.* This section implements section 1903(i)(2)(C) of the Act which prohibits payment of FFP with respect to items or services furnished by an individual or entity with respect to which there is pending an investigation of a credible allegation of fraud except under specified circumstances.

(b) *Denial of FFP.* No FFP is available with respect to any amount expended for an item or service furnished by any individual or entity to whom a State has failed to suspend payments in whole or part as required by § 455.23 of this chapter unless—

(1) The item or service is furnished as an emergency item or service, but not including items or services furnished in an emergency room of a hospital; or

(2) The State determines and documents that good cause as specified at § 455.23(e) or (f) of this chapter exists not to suspend such payments, to suspend payments only in part, or to discontinue a previously imposed payment suspension.

[76 FR 5965, Feb. 2, 2011]

### Subpart B—Payment Methods: General Provisions

#### § 447.200 Basis and purpose.

This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the Act, which requires that payments for services be consistent with efficiency, economy, and quality of care.

[46 FR 48560, Oct. 1, 1981]

#### § 447.201 State plan requirements.

(a) A State plan must provide that the requirements in this subpart are met.

(b) The plan must describe the policy and the methods to be used in setting payment rates for each type of service included in the State's Medicaid program.

#### § 447.202 Audits.

The Medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials.

#### § 447.203 Documentation of payment rates.

(a) The agency must maintain documentation of payment rates and make it available to HHS upon request.

(b) The agency must record, in State manuals or other official files, the following information for increases in payment rates for individual practitioner services:

(1) An estimate of the percentile of the range of customary charges to which the revised payment structure equates and a description of the methods used to make the estimate.

(2) An estimate of the composite average percentage increase of the revised payment rates over the preceding rates.

#### § 447.204 Encouragement of provider participation.

The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to beneficiaries at least to the extent that those services are available to the general population.

#### § 447.205 Public notice of changes in Statewide methods and standards for setting payment rates.

(a) *When notice is required.* Except as specified in paragraph (b) of this section, the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services.

(b) *When notice is not required.* Notice is not required if—

(1) The change is being made to conform to Medicare methods or levels of reimbursement;

(2) The change is required by court order; or

(3) The change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost plus a professional fee.

(c) *Content of notice.* The notice must—

(1) Describe the proposed change in methods and standards;

(2) Give an estimate of any expected increase or decrease in annual aggregate expenditures;

(3) Explain why the agency is changing its methods and standards;

(4) Identify a local agency in each county (such as the social services agency or health department) where copies of the proposed changes are available for public review;

(5) Give an address where written comments may be sent and reviewed by the public; and

(6) If there are public hearings, give the location, date and time for hearings or tell how this information may be obtained.

(d) *Publication of notice.* The notice must—

(1) Be published before the proposed effective date of the change; and

(2) Appear as a public announcement in one of the following publications:

(i) A State register similar to the FEDERAL REGISTER.

(ii) The newspaper of widest circulation in each city with a population of 50,000 or more.

(iii) The newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more.

[46 FR 58680, Dec. 3, 1981; 47 FR 8567, Mar. 1, 1982, as amended at 48 FR 56057, Dec. 19, 1983]

**§ 447.250**

**42 CFR Ch. IV (10–1–15 Edition)**

**Subpart C—Payment for Inpatient  
Hospital and Long-Term Care  
Facility Services**

SOURCE: 46 FR 47971, Sept. 30, 1981, unless otherwise noted.

**§ 447.250 Basis and purpose.**

(a) This subpart implements section 1902(a)(13)(A) of the Act, which requires that the State plan provide for payment for hospital and long-term care facility services through the use of rates that the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated facilities to provide services in conformity with State and Federal laws, regulations, and quality and safety standards.

(b) Section 447.253(a)(2) implements section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care;

(c) Sections 447.253 (c) and (d) implement sections 1902(a)(13)(B) and 1902(a)(13)(C) of the Act, which require a State Medicaid agency to make certain assurances to the Secretary regarding increases in payments resulting solely from changes in ownerships of hospitals, NFs, and ICFs/IID.

(d) Section 447.271 implements section 1903(i)(3) of the Act, which requires that payments for inpatient hospital services not exceed the hospital's customary charges.

(e) Section 447.280 implements section 1913(b) of the Act, which concerns reimbursement for long-term care services furnished by swing-bed hospitals.

[48 FR 56057, Dec. 19, 1983, as amended at 57 FR 43921, Sept. 23, 1992]

**PAYMENT RATES**

**§ 447.251 Definitions.**

For the purposes of this subpart—

*Long-term care facility services* means intermediate care facility services for Individuals with Intellectual Disabilities (ICF/IID) and nursing facility (NF) services.

*Provider* means an institution that furnishes inpatient hospital services or

an institution that furnishes long-term care facility services.

[46 FR 47971, Sept. 30, 1981, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991]

**§ 447.252 State plan requirements.**

(a) The plan must provide that the requirements of this subpart are met.

(b) The plan must specify comprehensively the methods and standards used by the agency to set payment rates in a manner consistent with § 430.10 of this chapter.

(c) If the agency chooses to apply the cost limits established under Medicare (see § 413.30 of this chapter) on an individual provider basis, the plan must specify this requirement.

(Approved by the Office of Management and Budget under control number 0938–0193)

[48 FR 56058, Dec. 19, 1983, as amended at 51 FR 34833, Sept. 30, 1986]

**§ 447.253 Other requirements.**

(a) *State assurances.* In order to receive CMS approval of a State plan change in payment methods and standards, the Medicaid agency must make assurances satisfactory to CMS that the requirements set forth in paragraphs (b) through (i) of this section are being met, must submit the related information required by § 447.255 of this subpart, and must comply with all other requirements of this subpart.

(b) *Findings.* Whenever the Medicaid agency makes a change in its methods and standards, but not less often than annually, the agency must make the following findings:

(1) *Payment rates.* (i) The Medicaid agency pays for inpatient hospital services and long-term care facility services through the use of rates that are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations, and quality and safety standards.

(ii) With respect to inpatient hospital services—

(A) The methods and standards used to determine payment rates take into account the situation of hospitals which serve a disproportionate number

of low income patients with special needs;

(B) If a State elects in its State plan to cover inappropriate level of care services (that is, services furnished to hospital inpatients who require a lower covered level of care such as skilled nursing or intermediate care services) under conditions similar to those described in section 1861(v)(1)(G) of the Act, the methods and standards used to determine payment rates must specify that the payments for this type of care must be made at rates lower than those for inpatient hospital level of care services, reflecting the level of care actually received, in a manner consistent with section 1861(v)(1)(G) of the Act; and

(C) The payment rates are adequate to assure that beneficiaries have reasonable access, taking into account geographic location and reasonable travel time, to inpatient hospital services of adequate quality.

(iii) With respect to nursing facility services—

(A) Except for preadmission screening for individuals with mental illness and Intellectual Disability under § 483.20(f) of this Chapter, the methods and standards used to determine payment rates take into account the costs of complying with the requirements of part 483 subpart B of this chapter;

(B) The methods and standards used to determine payment rates provide for an appropriate reduction to take into account the lower costs (if any) of the facility for nursing care under a waiver of the requirement in § 483.30(c) of this Chapter to provide licensed nurses on a 24-hour basis;

(C) The State establishes procedures under which the data and methodology used in establishing payment rates are made available to the public.

(2) *Upper payment limits.* The agency's proposed payment rate will not exceed the upper payment limits as specified in § 447.272.

(c) *Changes in ownership of hospitals.* In determining payment when there has been a sale or transfer of the assets of a hospital, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate solely as a result of changes of ownership, more

than the payments would increase under Medicare under §§ 413.130, 413.134, 413.153, and 413.157 of this chapter, insofar as these sections affect payments for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(d) *Changes in ownership of NFs and ICFs/IID.* In determining payment when there has been a sale or transfer of assets of an NF or ICF/IID, the State's methods and standards must provide the following depending upon the date of the transfer.

(1) For transfers on or after July 18, 1984 but before October 1, 1985, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate, solely as the result of a change in ownership, more than payments would increase under Medicare under §§ 413.130, 413.134, 413.153 and 413.157 of this chapter, insofar as these sections affect payment for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(2) For transfers on or after October 1, 1985, the State's methods and standards must provide that the valuation of capital assets for purposes of determining payment rates for NFs and ICFs/IID is not to increase (as measured from the date of acquisition by the seller to the date of the change of ownership) solely as a result of a change of ownership, by more than the lesser of—

(i) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership, or, if necessary, as extrapolated retrospectively by the Secretary) in the Dodge construction index applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year; or

(ii) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of

## § 447.255

the change of ownership) in the Consumer Price Index for All Urban Consumers (CPI-U) (United States city average) applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year.

(e) *Provider appeals.* The Medicaid agency must provide an appeals or exception procedure that allows individual providers an opportunity to submit additional evidence and receive prompt administrative review, with respect to such issues as the agency determines appropriate, of payment rates.

(f) *Uniform cost reporting.* The Medicaid agency must provide for the filing of uniform cost reports by each participating provider.

(g) *Audit requirements.* The Medicaid agency must provide for periodic audits of the financial and statistical records of participating providers.

(h) *Public notice.* The Medicaid agency must provide that it has complied with the public notice requirements in § 447.205 of this part when it is proposing significant changes to its methods or standards for setting payment rates for inpatient hospital or LTC facility services.

(i) *Rates paid.* The Medicaid agency must pay for inpatient hospital and long term care services using rates determined in accordance with methods and standards specified in an approved State plan.

[48 FR 56057, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987; 54 FR 5359, Feb. 2, 1989; 57 FR 43921, Sept. 23, 1992]

## § 447.255 Related information.

The Medicaid agency must submit, with the assurances described in § 447.253(a), the following information:

(a) The amount of the estimated average proposed payment rate for each type of provider (hospital, ICF/IID, or nursing facility), and the amount by which that estimated average rate increased or decreased relative to the average payment rate in effect for each type or provider for the immediately preceding rate period;

(b) An estimate of the short-term and, to the extent feasible, long-term effect the change in the estimated average rate will have on—

## 42 CFR Ch. IV (10–1–15 Edition)

(1) The availability of services on a Statewide and geographic area basis;

(2) The type of care furnished;

(3) The extent of provider participation; and

(4) The degree to which costs are covered in hospitals that serve a disproportionate number of low income patients with special needs.

[48 FR 56058, Dec. 19, 1983, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991; 57 FR 43924, Sept. 23, 1992; 57 FR 46431, Oct. 8, 1992]

## § 447.256 Procedures for CMS action on assurances and State plan amendments.

(a) *Criteria for approval.* (1) CMS approval action on State plans and State plan amendments, is taken in accordance with subpart B of part 430 of this chapter and sections 1116, 1902(b) and 1915(f) of the Act.

(2) In the case of State plan and plan amendment changes in payment methods and standards, CMS bases its approval on the acceptability of the Medicaid agency's assurances that the requirements of § 447.253 have been met, and the State's compliance with the other requirements of this subpart.

(b) *Time limit.* CMS will send a notice to the agency of its determination as to whether the assurances regarding a State plan amendment are acceptable within 90 days of the date CMS receives the assurances described in § 447.253, and the related information described in § 447.255 of this subpart. If CMS does not send a notice to the agency of its determination within this time limit and the provisions in paragraph (a) of this section are met, the assurances and/or the State plan amendment will be deemed accepted and approved.

(c) *Effective date.* A State plan amendment that is approved will become effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted in accordance with §§ 430.20 of this chapter and 447.253.

[48 FR 56058, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987]

## FEDERAL FINANCIAL PARTICIPATION

**§ 447.257 FFP: Conditions relating to institutional reimbursement.**

FFP is not available for a State's expenditures for hospital inpatient or long-term care facility services that are in excess of the amounts allowable under this subpart.

[52 FR 28147, July 28, 1987]

## UPPER LIMITS

**§ 447.271 Upper limits based on customary charges.**

(a) Except as provided in paragraph (b) of this section, the agency may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(b) The agency may pay a public provider that provides services free or at a nominal charge at the same rate that would be used if the provider charges were equal to or greater than its costs.

[75 FR 73975, Nov. 30, 2010]

**§ 447.272 Inpatient services: Application of upper payment limits.**

(a) *Scope.* This section applies to rates set by the agency to pay for inpatient services furnished by hospitals, NFs, and ICFs/IID within one of the following categories:

(1) State government-owned or operated facilities (that is, all facilities that are either owned or operated by the State).

(2) Non-State government-owned or operated facilities (that is, all government facilities that are neither owned nor operated by the State).

(3) Privately-owned and operated facilities.

(b) *General rules.* (1) Upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) Except as provided for in paragraph (c) of this section, aggregate Medicaid payments to a group of facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(c) *Exceptions*—(1) *Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93-638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For non-State government owned or operated hospitals,—March 19, 2002.

(2) For all other facilities—March 13, 2001.

[66 FR 3175, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2610, Jan. 18, 2002; 72 FR 29834, May 29, 2007; 75 FR 73975, Nov. 30, 2010; 77 FR 31512, May 29, 2012]

## SWING-BED HOSPITALS

**§ 447.280 Hospital providers of NF services (swing-bed hospitals).**

(a) *General rule.* If the State plan provides for NF services furnished by a swing-bed hospital, as specified in §§ 440.40(a) and 440.150(f) of this chapter, the methods and standards used to determine payment rates for routine NF services must—

(1) Provide for payment at the average rate per patient day paid to NFs, as applicable, for routine services furnished during the previous calendar year; or

(2) Meet the State plan and payment requirements described in this subpart, as applicable.

(b) *Application of the rule.* The payment methodology used by a State to set payment rates for routine NF services must apply to all swing-bed hospitals in the State.

[59 FR 56237, Nov. 10, 1994]

### Subpart D [Reserved]

## Subpart E—Payment Adjustments for Hospitals That Serve a Disproportionate Number of Low-Income Patients

SOURCE: 57 FR 55143, Nov. 24, 1992, unless otherwise noted.

### § 447.294 Medicaid disproportionate share hospital (DSH) allotment reductions for Federal fiscal year 2014 and Federal fiscal year 2015.

(a) *Basis and purpose.* This section sets forth the DSH health reform methodology (DHRM) for calculating State-specific annual DSH allotment reductions from Federal fiscal year 2014 and Federal fiscal year 2015 as required under section 1923(f) of the Act.

(b) *Definitions.* For purposes of this section—

*Aggregate DSH allotment reductions* mean the amounts identified in section 1923(f)(7)(A)(ii) of the Act.

*Budget neutrality factor (BNF)* is a factor incorporated in the DHRM that takes into account the extent to which the DSH allotment for a State was included in the budget neutrality calculation for a coverage expansion approved under section 1115 as of July 31, 2009.

*DSH payment* means the amount reported in accordance with § 447.299(c)(17).

*Effective DSH allotment* means the amount of DSH allotment determined by subtracting the State-specific DSH allotment reduction from a State's unreduced DSH allotment.

*High level of uncompensated care factor (HUF)* is a factor incorporated in the DHRM that results in larger percentage DSH allotment reduction for States that do not target DSH pay-

ments on hospitals with high levels of uncompensated care.

*High Medicaid volume hospital* means a disproportionate share hospital that has an MIUR at least one standard deviation above the mean MIUR for hospitals receiving Medicaid payments in the State.

*High uncompensated care hospital* means a hospital that exceeds the mean ratio of uncompensated care costs to total Medicaid and uninsured inpatient and outpatient hospital service costs for all disproportionate share hospitals within a state.

*High volume of Medicaid inpatients factor (HMF)* is a factor incorporated in the DHRM that results in larger percentage DSH allotment reduction for States that do not target DSH payments on hospitals with high volumes of Medicaid inpatients.

*Hospital with high volumes of Medicaid inpatients* means a disproportionate share hospital that meets the requirements of section 1923(b)(1)(A) of the Act.

*Low DSH adjustment factor (LDF)* is a factor incorporated in the DHRM that results in a smaller percentage DSH allotment reduction on low DSH States.

*Low DSH State* means a State that meets the criterion described in section 1923(f)(5)(B) of the Act.

*Mean HUF reduction percentage* is determined by calculating the quotient of each state's HUF reduction amount divided by its unreduced DSH allotment, then calculating the mean for each state group, then converting the result to a percentage.

*Medicaid inpatient utilization rate (MIUR)* means the rate defined in section 1923(b)(2) of the Act.

*Non-high Medicaid volume hospital* means a disproportionate share hospital that does not meet the requirements of section 1923(b)(1)(A) of the Act.

*State group* means similarly situated States that are collectively identified by DHRM as defined in § 447.294(e)(1).

*State-specific DSH allotment reduction* means the amount of annual DSH allotment reduction for a particular State as determined by the DHRM.

*Total Medicaid cost* means the amount for each hospital reported in accordance with § 447.299(c)(10).

*Total population* means the 1-year estimates data of the total non-institutionalized population identified by United States Census Bureau's American Community Survey.

*Total uninsured cost* means the amount reported for each DSH in accordance with § 447.299(c)(14).

*Uncompensated care cost* means the amount reported for each hospital in accordance with § 447.299(c)(16).

*Uncompensated care level* means a hospital's uncompensated care cost divided by the sum of its total Medicaid cost and its total uninsured cost.

*Unreduced DSH allotment* means the DSH allotment calculated under section 1923(f) of the Act prior to annual reductions under this section.

*Uninsured percentage factor (UPF)* is a factor incorporated in the DHRM that results in larger percentage DSH allotment reductions for States that have the lowest percentages of uninsured individuals.

*Uninsured population* means 1-year estimates data of the number of uninsured identified by United States Census Bureau's American Community Survey.

(c) *Aggregate DSH allotment reduction amounts.* The aggregate DSH allotment reduction amounts are as provided in section 1923(f)(7)(A)(ii) of the Act.

(d) *State data submission requirements.* States are required to submit the mean MIUR, determined in accordance with section 1923(b)(1)(A) of the Act, for all hospitals receiving Medicaid payments in the State and the value of one standard deviation above such mean. States must provide the data for State Plan Rate Year (SPRY) 2008, SPRY 2009, SPRY 2010, and SPRY 2011 by June 30, 2014. States must provide this data for each subsequent SPRY to CMS by June 30 of each year. To determine which SPRY's data the state must submit, subtract 3 years from the calendar year in which the data is due. For example, SPRY 2012 data must be submitted to CMS by June 30, 2015.

(e) *DHRM methodology.* Section 1923(f)(7) of the Act requires aggregate annual reduction amounts for FY 2014 and FY 2015 to be reduced through the DHRM. The DHRM is calculated on an annual basis based on the most recent data available to CMS at the time of

the calculation. The DHRM is determined as follows:

(1) *Establishing State groups.* For each FY, CMS will separate low-DSH States and non-low DSH states into distinct State groups.

(2) *Aggregate DSH allotment reduction allocation.* CMS will allocate a portion of the aggregate DSH allotment reductions to each State group by the following:

(i) Dividing the sum of each State group's preliminary unreduced DSH allotments by the sum of both State groups' preliminary unreduced DSH allotment amounts to determine a percentage.

(ii) Multiplying the value of paragraph (e)(2)(i) of this section by the aggregate DSH allotment reduction amount under paragraph (c) of this section for the applicable fiscal year.

(iii) Applying the low DSH adjustment factor under paragraph (e)(3) of this section.

(3) *Low DSH adjustment factor (LDF) calculation.* CMS will calculate the LDF by the following:

(i) Dividing each State's preliminary unreduced DSH allotment by their respective total Medicaid service expenditures.

(ii) Calculating for each State group the mean of all values determined in paragraph (e)(3)(i) of this section.

(iii) Dividing the value of paragraph (e)(3)(ii) of this section for the low-DSH State group by the value of paragraph (e)(3)(ii) for the non-low DSH state group.

(4) *LDF application.* CMS will determine the final aggregate DSH allotment reduction allocation for each State group through application of the LDF by the following:

(i) Multiplying the LDF by the aggregate DSH allotment reduction for the low DSH State group.

(ii) Utilizing the value of paragraph (e)(4)(i) of this section as the aggregate DSH allotment reduction allocated to the low DSH State group.

(iii) Subtracting the value of paragraph (e)(4)(ii) of this section from the value of paragraph (e)(2)(ii) of this section for the low DSH State group; and

(iv) Adding the value of paragraph (e)(4)(iii) of this section to the value of



paragraph (e)(2)(ii) of this section for the non-low DSH State group.

(5) *Reduction factor allocation.* CMS will allocate the aggregate DSH allotment reduction amount to three core factors by multiply the aggregate DSH allotment reduction amount for each State group by the following:

- (i) UPF—33 and  $\frac{1}{3}$  percent.
- (ii) HMF—33 and  $\frac{1}{3}$  percent.
- (iii) HUF—33 and  $\frac{1}{3}$  percent.

(6) *Uninsured percentage factor (UPF) calculation.* CMS will calculate the UPF by the following:

(i) Dividing the total State population by the uninsured in State for each State.

(ii) Determining the uninsured reduction allocation component for each State as a percentage by dividing each State's value of paragraph (e)(6)(i) of this section by the sum of the values of paragraph (e)(6)(i) of this section for the respective State group (the sum of the values of all States in the State group should total 100 percent).

(iii) Determine a weighting factor by dividing each State's unreduced DSH allotment by the sum of all preliminary unreduced DSH allotments for the respective State group.

(iv) Multiply the weighting factor calculated in (e)(6)(iii) of this section by the value of each State's uninsured reduction allocation component from paragraph (e)(6)(ii) of this section.

(v) Determine the UPF as a percentage by dividing the product of paragraph (e)(6)(iv) of this section for each State by the sum of the values of paragraph (e)(6)(iv) of this section for the respective State group (the sum of the values of all States in the State group should total 100 percent).

(7) *UPF application and reduction amount.* CMS will determine the UPF portion of the final aggregate DSH allotment reduction allocation for each State by multiplying the State's UPF by the aggregate DSH allotment reduction allocated to the UPF factor under paragraph (e)(5) of this section for the respective State group.

(8) *High volume of Medicaid inpatients factor (HMF) calculation.* CMS will calculate the HMF by determining a percentage for each State by dividing the State's total DSH payments made to non-high Medicaid volume hospitals by

the total of such payments for the entire State group.

(9) *HMF application and reduction amount.* CMS will determine the HMF portion of the final aggregate DSH allotment reduction allocation for each State by multiplying the State's HMF by the aggregate DSH allotment reduction allocated to the HMF factor under paragraph (e)(5) of this section for the respective State group.

(10) *High level of uncompensated care factor (HUF) calculation.* CMS will calculate the HUF by determining a percentage for each State by dividing the State's total DSH payments made to non-High Uncompensated Care Level hospitals by the total of such payments for the entire State group.

(11) *HUF application and reduction amount.* CMS will determine the HUF portion of the final aggregate DSH allotment reduction allocation by multiplying each State's HUF by the aggregate DSH allotment reduction allocated to the HUF factor under paragraph (e)(5) of this section for the respective State group.

(12) *Section 1115 budget neutrality factor (BNF) calculation.* This factor is only calculated for States for which all or a portion of the DSH allotment was included in the calculation of budget neutrality under a section 1115 demonstration for the specific fiscal year subject to reduction pursuant to an approval on or before July 31, 2009. CMS will calculate the BNF for qualifying states by the following:

(i) For States whose DSH allotment was included in the budget neutrality calculation for a coverage expansion that was approved under section 1115 as of July 31, 2009, (without regard to approved amendments since that date) determining the amount of the State's DSH allotment included in the budget neutrality calculation for coverage expansion for the specific fiscal year subject to reduction. This amount is not subject to reductions under the HMF and HUF calculations.

(ii) Determining the amount of the State's DSH allotment included in the budget neutrality calculation for non-coverage expansion purposes for the specific fiscal year subject to reduction.

(iii) Multiplying each qualifying State's value of paragraph (e)(12)(ii) of this section by the mean HMF reduction percentage for the respective State group.

(iv) Multiplying each qualifying State's value of paragraph (e)(12)(ii) of this section by the mean HUF reduction percentage for the respective State group.

(v) For each State, calculating the sum of the value of paragraphs (e)(12)(iii) and of (e)(12)(iv) of this section.

(13) *Section 1115 budget neutrality factor (BNF) application.* This factor will be applied in the State-specific DSH allotment reduction calculation.

(14) *State-specific DSH allotment reduction calculation.* CMS will calculate the state-specific DSH reduction by the following:

(i) Taking the sum of the value of paragraphs (e)(7), (e)(9), and (e)(11) of this section for each State.

(ii) For States qualifying under paragraph (e)(12) of this section, adding the value of paragraph (e)(12)(v) of this section.

(iii) Reducing the amount of paragraph (e)(14)(i) of this section for each State that does not qualify under paragraph (e)(12)(v) of this section based on the proportion of each State's preliminary unreduced DSH allotment compared to the national total of preliminary unreduced DSH allotments so that the sum of paragraph (e)(14)(iii) of this section equals the sum of paragraph (e)(12)(v) of this section.

(f) *Annual DSH allotment reduction application.* For each fiscal year 2014 and fiscal year 2015, CMS will subtract the State-specific DSH allotment amount determined in paragraph (e)(14) of this section from that State's final unreduced DSH allotment. This amount is the State's final DSH allotment for the fiscal year.

[78 FR 57311, Sept. 18, 2013]

**§ 447.295 Hospital-specific disproportionate share hospital payment limit: Determination of individuals without health insurance or other third party coverage.**

(a) *Basis and purpose.* This section sets forth the methodology for determining the costs for individuals who

have no health insurance or other source of third party coverage for services furnished during the year for purposes of calculating the hospital-specific disproportionate share hospital payment limit under section 1923(g) of the Act.

(b) *Definitions.*

*Health insurance coverage limit* means a limit imposed by a third party payer that establishes a maximum dollar value or maximum number of specific services, for benefits received by an individual.

*Individuals who have no health insurance (or other source of third party coverage) for the services furnished during the year* means individuals who have no source of third party coverage for the specific inpatient hospital or outpatient hospital service furnished by the hospital.

*No source of third party coverage for a specific inpatient hospital or outpatient hospital service* means that the service is not included in an individual's health benefits coverage through a group health plan or health insurer, and for which there is no other legally liable third party. When a health insurance coverage limit is imposed by a third party payer, specific services beyond the limit would not be within the individual's health benefit package from that third party payer. For American Indians/Alaska Natives, IHS and tribal coverage is only considered third party coverage when services are received directly from IHS or tribal health programs (direct health care services) or when IHS or a tribal health program has authorized coverage through the contract health service program (through a purchase order or equivalent document). Administrative denials of payment, or requirements for satisfaction of deductible, copayment or coinsurance liability, do not affect the determination that a specific service is included in the health benefits coverage.

(c) *Determination of an individual's third party coverage status.* Individuals who have no source of third party coverage for a specific inpatient hospital or outpatient hospital service must be considered, for purposes of that service, to be uninsured. This determination is

not dependent on the receipt of payment by the hospital from the third party.

(1) The determination of an individual's status as having a source of third party coverage must be a service-specific coverage determination. The service-specific coverage determination can occur only once per individual per service provided and applies to the entire service, including all elements as that service, or similar services, would be defined in Medicaid.

(2) Individuals who are inmates in a public institution or are otherwise involuntarily in secure custody as a result of criminal charges are considered to have a source of third party coverage.

(d) *Hospital-specific DSH limit calculation.* Only costs incurred in providing inpatient hospital and outpatient hospital services to Medicaid individuals, and revenues received with respect to those services, and costs incurred in providing inpatient hospital and outpatient hospital services, and revenues received with respect to those services, for which a determination has been made in accordance with paragraph (c) of this section that the services were furnished to individuals who have no source of third party coverage for the specific inpatient hospital or outpatient hospital service are included when calculating the costs and revenues for Medicaid individuals and individuals who have no health insurance or other source of third party coverage for purposes of section 1923(g)(1) of the Act.

[79 FR 71694, Dec. 3, 2014]

**§ 447.296 Limitations on aggregate payments for disproportionate share hospitals for the period January 1, 1992 through September 30, 1992.**

(a) The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) For the period January 1, 1992 through September 30, 1992, FFP is available for aggregate payments to hospitals that serve a disproportionate number of low-income patients with

special needs only if the payments are made in accordance with sections 1902(a)(13)(A) and 1923 of the Act, and with one of the following:

(1) An approved State plan in effect as of September 30, 1991.

(2) A State plan amendment submitted to CMS by September 30, 1991.

(3) A State plan amendment, or modification thereof, submitted to CMS between October 1, 1991 and November 26, 1991, if the amendment, or modification thereof, was intended to limit the State's definition of disproportionate share hospitals to those hospitals with Medicaid inpatient utilization rates or low-income utilization rates (as defined in section 1923 (b) of the Act) at or above the statewide arithmetic mean.

(4) A methodology for disproportionate share hospital payments that was established and in effect as of September 30, 1991, or in accordance with a State law enacted or State regulation adopted as of September 30, 1991.

(5) A State plan amendment submitted to CMS by September 30, 1992 that increases aggregate disproportionate share hospitals payments in order to meet the minimum payment adjustments required by section 1923(c)(1) of the Act. The minimum payment adjustment is the amount required by the Medicare methodology described in section 1923(c)(1) of the Act for those hospitals that satisfy the minimum Federal definition of a disproportionate share hospital in section 1923(b) of the Act.

(6) A State plan amendment submitted to CMS by September 30, 1992 that provides for a redistribution of disproportionate share hospital payments within the State without raising total payments compared to the previously approved State plan. CMS will approve the amendment only if the State submits written documentation that demonstrates to CMS that the aggregate payments that will be made after the redistribution are no greater than those payments made before the redistribution.

(7) A State plan amendment submitted to CMS by September 30, 1992 that provides for a reduction in disproportionate share hospital payments.

**§ 447.297 Limitations on aggregate payments for disproportionate share hospitals beginning October 1, 1992.**

(a) *Applicability.* The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) *National payment target.* The national payment target for disproportionate share hospital (DSH) payments for any Federal fiscal year is equal to 12 percent of the total medical assistance expenditures that will be made during the Federal fiscal year under State plans, excluding administrative costs. A preliminary national expenditure target will be published by CMS prior to October 1 of each year. This preliminary national expenditure target will be superseded by a final national expenditure target published by April 1 of each Federal fiscal year, as specified in paragraph (d) of this section.

(c) *State disproportionate share hospital allotments.* Prior to October 1 of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER preliminary State DSH allotments for each State. These preliminary State DSH allotments will be determined using the most current applicable actual and estimated State expenditure information as reported to CMS and adjusted by CMS as may be necessary using the methodology described in § 447.298. CMS will publish final State DSH allotments by April 1 of each Federal fiscal year, as described in paragraph (d) of this section.

(d) *Final national disproportionate share hospitals expenditure target and State disproportionate share hospitals allotments.* (1) CMS will revise the preliminary national expenditure target and the preliminary State DSH allotments by April 1 of each Federal fiscal year. The final national DSH expenditure target and State DSH allotments will be based on the most current applicable actual and estimated expenditure information reported to CMS and adjusted by CMS as may be necessary immediately prior to the April 1 publication date. The final national expenditure target and State DSH allotments

will not be recalculated for that Federal fiscal year based upon any subsequent actual or estimated expenditure information reported to CMS.

(2) If CMS determines that at any time a State has exceeded its final DSH allotment for a Federal fiscal year, FFP attributable to the excess DSH expenditures will be disallowed.

(3) If a State's actual DSH expenditures applicable to a Federal fiscal year are less than its final State DSH allotment for that Federal fiscal year, the State is permitted, to the extent allowed by its approved State plan, to make additional DSH expenditures applicable to that Federal fiscal year up to the amount of its final DSH allotment for that Federal fiscal year.

(e) *Publication of limits.* (1) Before the beginning of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER—

(i) A preliminary national DSH expenditure target for the Federal fiscal year; and

(ii) A preliminary DSH allotment for each State for the Federal fiscal year.

(2) The final national DSH expenditure target and State DSH allotments will be published in the FEDERAL REGISTER by April 1 of each Federal fiscal year.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

**§ 447.298 State disproportionate share hospital allotments.**

(a) *Calculation of State's base allotment for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate for each State a DSH allotment, using the State's "base allotment." The State's base allotment is the greater of:

(i) The total amount of the State's projected DSH payments for Federal fiscal year 1992 under the State plan applicable to Federal fiscal year 1992, calculated in accordance with paragraph (a)(2) of this section; or

(ii) \$1,000,000.

(2) In calculating the State's DSH payments applicable to Federal fiscal year 1992, CMS will derive amounts from payments applicable to the period of October 1, 1991, through September 30, 1992, under State plans or plan

amendments that meet the requirements specified in § 447.296(b). The calculation will not include—

(i) DSH payment adjustments made by the State applicable to the period October 1, 1991 through December 31, 1991 under State plans or plan amendments that do not meet the criteria described in § 447.296; and

(ii) Retroactive DSH payments made in 1992 that are not applicable to Federal fiscal year 1992.

(3) CMS will calculate a percentage for each State by dividing the DSH base allotment by the total unadjusted medical assistance expenditures, excluding administrative costs, made during Federal fiscal year 1992. On the basis of this percentage, CMS will classify each State as a “high-DSH” or “low-DSH” State.

(i) If the State’s base allotment exceeded 12 percent of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a “high-DSH” State.

(ii) If the State’s base allotment was 12 percent or less of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a “low-DSH” State.

(b) *State disproportionate share hospital allotments for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate a DSH allotment for each low-DSH State that equals the State’s base allotment described under paragraph (a) of this section, increased by State growth, as specified in paragraph (d) of this section.

(2) For high-DSH States, the dollar amount of DSH payments in Federal fiscal year 1993 may not exceed the dollar amount of DSH payments applicable to Federal fiscal year 1992 (that is, the State base allotment).

(c) *State disproportionate share hospital allotment for Federal fiscal years 1994 and after.* For Federal fiscal years 1994 and after—

(1) For low-DSH States, CMS will calculate the DSH allotment for each Federal fiscal year by increasing the prior year’s State DSHs allotment by—

(i) State growth, as specified in paragraph (d) of this section; and

(ii) A supplemental amount, if applicable, as described in paragraph (e) of this section.

(2) For high-DSH States, the dollar amount of DSH payments applicable to any Federal fiscal year may not exceed the dollar amount of payments applicable to Federal fiscal year 1992 (that is, the State base allotment). This payment limitation will apply until the Federal fiscal year in which the State’s DSH payments applicable to that Federal fiscal year, expressed as a percentage of the State’s total unadjusted medical assistance expenditures in that Federal fiscal year, equal 12 percent or less. When a high-DSH State’s percentage equals 12 percent or less, the State will be reclassified as a low-DSH State.

(d) *State growth.* (1) The State growth for a State in a Federal fiscal year is equal to the product of—

(i) The growth factor that is CMS’s projected percentage increase in the State’s total unadjusted medical assistance expenditures (including administrative costs) relative to the corresponding amount in the previous year; and

(ii) The State’s prior year DSH allotment.

(2) If the growth factor is zero or is negative, the State growth is zero.

(3) If a low-DSH State experiences a level of negative growth to the extent that its previous Federal fiscal year’s DSH allotment would be more than 12 percent of its current Federal fiscal year’s total unadjusted medical assistance expenditures (excluding administrative costs), the low-DSH State’s previous year’s DSH allotment will be reduced to the extent necessary to maintain the individual low-DSH State’s 12-percent limit and that amount will become the low-DSH State’s DSH allotment for the current Federal fiscal year. In no Federal fiscal year will a low-DSH State’s DSH allotment be allowed to exceed its individual State 12-percent limit.

(e) *Supplemental amount available for low-DSH States.* (1) A supplemental amount is the State’s share of a pool of money (referred to as a redistribution pool).

(2) CMS will calculate the redistribution pool for the appropriate Federal

fiscal year by subtracting from the projected national DSH expenditure target the following:

(i) The total of the State DSH base allotments for all high-DSH States;

(ii) The total of the previous year's State DSH allotments for all low-DSH States;

(iii) The State growth amount for all low-DSH States; and

(iv) The total amount of additional DSH payment adjustments made in order to meet the minimum payment adjustments required under section 1923(c)(1) of the Act, which are made in accordance with § 447.296(b)(5).

(3) CMS will determine the percent of the redistribution pool for each low-DSH State on the basis of each State's relative share of the total unadjusted medical assistance expenditures for the Federal fiscal year compared to the total unadjusted medical assistance expenditures for the Federal fiscal year projected to be made by all low-DSH States. The percent of the redistribution pool that each State will receive is equal to the State's total unadjusted medical assistance expenditures divided by the total unadjusted medical assistance expenditures for all low-DSH States.

(4) CMS will not provide any low-DSH State a supplemental amount that would result in the State's total DSH allotment exceeding 12 percent of its projected total unadjusted medical assistance expenditures. CMS will reallocate any supplemental amounts not allocated to States because of this 12-percent limitation to other low-DSH States in accordance with the percentage determined in paragraph (e)(3) of this section.

(5) CMS will not reallocate to low-DSH States the difference between any State's actual DSH expenditures applicable to a Federal fiscal year and its State DSH allotment applicable to that Federal fiscal year. Thus, any unspent DSH allotment may not be reallocated.

(f) *Special provision.* Any increases in a State's aggregate disproportionate payments, that are made to meet the minimum payment requirements specified in § 447.296(b)(5), may exceed the State base allotment to the extent such increases are made to satisfy the minimum payment requirement. In

such cases, CMS will adjust the State's base allotment in the subsequent Federal fiscal year to include the increased minimum payments.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

#### § 447.299 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993, each State must submit to CMS the quarterly aggregate amount of its disproportionate share hospital payments made to each individual public and private provider or facility. States' reports must present a complete, accurate, and full disclosure of all of their DSH programs and expenditures.

(b) Each State must report the aggregate information specified under paragraph (a) of this section on a quarterly basis in accordance with procedures established by CMS.

(c) Beginning with each State's Medicaid State plan rate year 2005, for each Medicaid State plan rate year, the State must submit to CMS, at the same time as it submits the completed audit required under § 455.204, the following information for each DSH hospital to which the State made a DSH payment in order to permit verification of the appropriateness of such payments:

(1) *Hospital name.* The name of the hospital that received a DSH payment from the State, identifying facilities that are institutes for mental disease (IMDs) and facilities that are located out-of-state.

(2) *Estimate of hospital-specific DSH limit.* The State's estimate of eligible uncompensated care for the hospital receiving a DSH payment for the year under audit based on the State's methodology for determining such limit.

(3) *Medicaid inpatient utilization rate.* The hospital's Medicaid inpatient utilization rate, as defined in Section 1923(b)(2) of the Act, if the State does not use alternative qualification criteria described in paragraph (c)(5) of this section.

(4) *Low income utilization rate.* The hospital's low income utilization rate, as defined in Section 1923(b)(3) of the Act if the State does not use alternative qualification criteria described in paragraph (c)(5) of this section.

(5) *State defined DSH qualification criteria.* If the State uses an alternate broader DSH qualification methodology as authorized in Section 1923(b)(4) of the Act, the value of the statistic and the methodology used to determine that statistic.

(6) *IP/OP Medicaid fee-for-service (FFS) basic rate payments.* The total annual amount paid to the hospital under the State plan, including Medicaid FFS rate adjustments, but not including DSH payments or supplemental/enhanced Medicaid payments, for inpatient and outpatient services furnished to Medicaid eligible individuals.

(7) *IP/OP Medicaid managed care organization payments.* The total annual amount paid to the hospital by Medicaid managed care organizations for inpatient hospital and outpatient hospital services furnished to Medicaid eligible individuals.

(8) *Supplemental/enhanced Medicaid IP/OP payments.* Indicate the total annual amount of supplemental/enhanced Medicaid payments made to the hospital under the State plan. These amounts do not include DSH payments, regular Medicaid FFS rate payments, and Medicaid managed care organization payments.

(9) *Total Medicaid IP/OP Payments.* Provide the total sum of items identified in § 447.299(c)(6), (7) and (8).

(10) *Total Cost of Care for Medicaid IP/OP Services.* The total annual costs incurred by each hospital for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals.

(11) *Total Medicaid Uncompensated Care.* The total amount of uncompensated care attributable to Medicaid inpatient and outpatient services. The amount should be the result of subtracting the amount identified in § 447.299(c)(9) from the amount identified in § 447.299(c)(10). The uncompensated care costs of providing Medicaid physician services cannot be included in this amount.

(12) *Uninsured IP/OP revenue.* Total annual payments received by the hospital by or on behalf of individuals with no source of third party coverage for inpatient and outpatient hospital services they receive. This amount does not include payments made by a

State or units of local government, for services furnished to indigent patients.

(13) *Total Applicable Section 1011 Payments.* Federal Section 1011 payments for uncompensated inpatient and outpatient hospital services provided to Section 1011 eligible aliens with no source of third party coverage for the inpatient and outpatient hospital services they receive.

(14) *Total cost of IP/OP care for the uninsured.* Indicate the total costs incurred for furnishing inpatient hospital and outpatient hospital services to individuals with no source of third party coverage for the hospital services they receive.

(15) *Total uninsured IP/OP uncompensated care costs.* Total annual amount of uncompensated IP/OP care for furnishing inpatient hospital and outpatient hospital services to individuals with no source of third party coverage for the hospital services they receive.

(i) The amount should be the result of subtracting paragraphs (c)(12) and (c)(13), from paragraph (c)(14) of this section.

(ii) The uncompensated care costs of providing physician services to the uninsured cannot be included in this amount.

(iii) The uninsured uncompensated amount also cannot include amounts associated with unpaid co-pays or deductibles for individuals with third party coverage for the inpatient and/or outpatient hospital services they receive or any other unreimbursed costs associated with inpatient and/or outpatient hospital services provided to individuals with those services in their third party coverage benefit package.

(iv) The uncompensated care costs do not include bad debt or payer discounts related to services furnished to individuals who have health insurance or other third party payer.

(16) *Total annual uncompensated care costs.* The total annual uncompensated care cost equals the total cost of care for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals and to individuals with no source of third party coverage for the hospital services they receive less the sum of regular Medicaid FFS rate payments, Medicaid managed care organization payments,

## Centers for Medicare & Medicaid Services, HHS

## § 447.304

supplemental/enhanced Medicaid payments, uninsured revenues, and Section 1011 payments for inpatient and outpatient hospital services. This should equal the sum of paragraphs (c)(9), (c)(12), and (c)(13) subtracted from the sum of paragraphs (c)(10) and (c)(14) of this section.

(17) *Disproportionate share hospital payments.* Indicate total annual payment adjustments made to the hospital under Section 1923 of the Act.

(18) *Medicaid provider number.* The provider identification number assigned by the Medicaid program.

(19) *Medicare provider number.* The provider identification number assigned by the Medicare program.

(20) *Total hospital cost.* The total annual costs incurred by each hospital for furnishing inpatient hospital and outpatient hospital services.

(21) *Reporting.* States must report DSH payments made to all hospitals under the authority of the approved Medicaid State plan. This includes both in-State and out-of-State hospitals. For out-of-State hospitals, States must report, at a minimum, the information identified in § 447.299(c)(1) through (c)(6), (c)(8), (c)(9), (c)(17), (c)(18), and (c)(19).

(d) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description of each DSH program, the legal basis of each DSH program, and the amount of DSH payments made to each individual public and private provider or facility each quarter. This information must be made available to Federal reviewers upon request.

(e) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP CMS estimates is attributable to the expenditures made to the disproportionate share hospitals as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released

when the State complies with all reporting requirements.

[46 FR 47971, Sept. 30, 1981, as amended at 73 FR 77950, Dec. 19, 2008; 74 FR 18657, Apr. 24, 2009; 77 FR 31512, May 29, 2012; 78 FR 57313, Sept. 18, 2013]

### Subpart F—Payment Methods for Other Institutional and Non-institutional Services

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted. Redesignated at 46 FR 47973, Sept. 30, 1981, and further redesignated at 58 FR 6095, Jan. 26, 1993.

#### § 447.300 Basis and purpose.

In this subpart, §§ 447.302 through 447.325 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(15) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

[72 FR 39239, July 17, 2007]

#### § 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

[46 FR 48560, Oct. 1, 1981]

#### § 447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and co-insurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is not available for a State's expenditures for services that are in excess of the amounts allowable under this subpart.

NOTE: The Secretary may waive any limitation on reimbursement imposed by subpart F of this part for experiments conducted under section 402 of Pub. L. 90-428, Incentives for Economy Experimentation, as amended



## § 447.321

by section 222(b) of Pub. L. 92-603, and under section 222(a) of Pub. L. 92-603.

[46 FR 48560, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 66 FR 3176, Jan. 12, 2001]

### OUTPATIENT HOSPITAL AND CLINIC SERVICES

#### **§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.**

(a) *Scope.* This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:

(1) State government-owned or operated facilities (that is, all facilities that are owned or operated by the State.)

(2) Non-State government owned or operated facilities (that is, all government operated facilities that are neither owned nor operated by the State.)

(3) Privately-owned and operated facilities.

(b) *General rules.* (1) Upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to a group of facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(c) *Exceptions.* Indian Health Services and tribal facilities. The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93-638).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b)(1) of this section by one of the following dates:

(1) For non-State government-owned or operated hospitals—March 19, 2002.

## 42 CFR Ch. IV (10-1-15 Edition)

(2) For all other facilities—March 13, 2001.

[66 FR 3176, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2611, Jan. 18, 2002; 72 FR 29835, May 29, 2007; 75 FR 73975, Nov. 30, 2010; 77 FR 31513, May 29, 2012]

### OTHER INPATIENT AND OUTPATIENT FACILITIES

#### **§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.**

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

#### **§ 447.342 [Reserved]**

### PREPAID CAPITATION PLANS

#### **§ 447.362 Upper limits of payment: Nonrisk contract.**

Under a nonrisk contract, Medicaid payments to the contractor may not exceed—

(a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to beneficiaries: plus

(b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

### RURAL HEALTH CLINIC SERVICES

#### **§ 447.371 Services furnished by rural health clinics.**

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed,

governed, and supervised with other departments of the facility.

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in § 405.2426 of this chapter.

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.

(d) For purposes of paragraph (c) (1) and (3) of this section, “visit” means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 34833, Sept. 30, 1986]

## Subpart G—Payments for Primary Care Services Furnished by Physicians

SOURCE: 77 FR 66700, Nov. 6, 2012, unless otherwise noted.

### § 447.400 Primary care services furnished by physicians with a specified specialty or subspecialty.

(a) States pay for services furnished by a physician as defined in § 440.50 of this chapter, or under the personal supervision of a physician who self-attests to a specialty designation of family medicine, general internal medicine or pediatric medicine or a subspecialty recognized by the American Board of Medical Specialties (ABMS), the American Board of Physician Specialties (ABPS) or the American Osteopathic Association (AOA). Such physician then attests that he/she:

(1) Is Board certified with such a specialty or subspecialty and/or

(2) Has furnished evaluation and management services and vaccine administration services under codes described in paragraph (b) of this section that equal at least 60 percent of the Medicaid codes he or she has billed during the most recently completed CY or, for newly eligible physicians, the prior month.

(b) At the end of CY 2013 and 2014 the Medicaid agency must review a statistically valid sample of physicians who received higher payments to verify that they meet the requirements of paragraph (a)(1) or (2) of this section.

(c) Primary care services designated in the Healthcare Common Procedure Coding System (HCPCS) are as follows:

(1) Evaluation and Management (E&M) codes 99201 through 99499.

(2) Current Procedural Terminology (CPT) vaccine administration codes 90460, 90461, 90471, 90472, 90473 and 90474, or their successor codes.

(d)(1) The state must submit to CMS, in such form and at such time as CMS specifies, information relating to participation by physicians described in paragraph (a) of this section and the utilization of E&M codes described in paragraph (c) of this section (whether furnished by or under the supervision of a physician described in paragraph

#### § 447.405

#### 42 CFR Ch. IV (10–1–15 Edition)

(a)) of this section for the following periods—

- (i) As of July 1, 2009, and
- (ii) CY 2013

(2) As soon as practicable after receipt, CMS will post this information on *www.Medicaid.gov*.

[77 FR 66700, Nov. 6, 2012, as amended at 77 FR 74382, Dec. 14, 2012]

#### § 447.405 Amount of required minimum payments.

(a) For CYs 2013 and 2014, a state must pay for physician services described in § 447.400 based on the lower of:

(1) The Medicare Part B fee schedule rate that is applicable to the specific site of service or, at the state's option, the office setting and is also adjusted for either the specific geographic location of the service or reflects the mean over all counties of the rate for each E&M code. If there is no applicable rate, the rate specified in a fee schedule established and announced by CMS (that is, the product of multiplying the Medicare CF in effect at the beginning of CYs 2013 or 2014 (or the CY 2009 CF, if higher) and the CY 2013 and 2014 relative value units (RVUs).

(2) The provider's actual billed charge for the service.

(b) For vaccines provided under the Vaccines for Children Program in CYs 2013 and 2014, a State must pay the lesser of:

(1) The Regional Maximum Administration Fee; or,

(2) The Medicare fee schedule rate in CY 2013 or 2014 (or, if higher, the rate using the 2009 conversion factor and the 2013 and 2014 RVUs) for code 90460.

[77 FR 66700, Nov. 6, 2012, as amended at 77 FR 74382, Dec. 14, 2012]

#### § 447.410 State plan requirements.

The state must amend its state plan to reflect the increase in fee schedule payments in CYs 2013 and 2014 unless, for each of the billing codes eligible for payment, the state currently reimburses at least as much as the higher of the CY 2013 and CY 2014 Medicare rate or the rate that would be derived using the CY 2009 conversion factor and the CY 2013 and 2014 Medicare relative value units (RVUs). The amendment must:

(a) Identify all eligible codes that the state will reimburse at the Medicare rate in CYs 2013 and 2014.

(b) Identify all codes that were not reimbursed under the Medicaid program as of July 1, 2009.

(c) Specify either that the state will make all adjustments applicable to the specific site of service or, at the state's option, the office setting and will also either adjust for the specific geographic location of the service or pay rates that reflect the mean over all counties of the rate for each E&M code. The state must specify the formula that the state will use to determine the mean rate for each E&M code.

#### § 447.415 Availability of Federal financial participation (FFP).

(a) For primary care services furnished by physicians specified in § 447.400, FFP will be available at the rate of 100 percent for the amount by which the payment required to comply with § 447.405 exceeds the Medicaid payment that would have been made under the approved state plan in effect on July 1, 2009.

(b) For purposes of calculating the payment that would have been made under the approved State plan in effect on July 1, 2009, the state must exclude incentive, bonus, and performance-based payments but must include supplemental payments for which the approved methodology is linked to volume and payment for specific codes.

(c) For vaccine administration, the state must impute the payment that would have been made for code 90460 under the approved Medicaid state plan. The imputed rate for July 1, 2009, for code 90460 equals the payment rates for codes 90465 and 90471 weighted by service volume.

(d) For any payment made under a bundled rate methodology, including bundled rates for vaccines and vaccine administration, the amount directly attributable to the applicable primary care service must be isolated for purposes of determining the availability of the 100 percent FFP rate. Bundled rates, for purposes of this provision, do not include encounter and per diem rates.

#### Subpart H [Reserved]

**Subpart I—Payment for Drugs**

SOURCE: 72 FR 39239, July 17, 2007, unless otherwise noted.

**§ 447.500 Basis and purpose.**

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.

**§ 447.502 Definitions.**

*Bona fide service fees* mean fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

*Brand name drug* means a single source or innovator multiple source drug.

*Bundled sale* means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs

been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.

*Consumer Price Index—Urban (CPI-U)* means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

*Dispensing fee* means the fee which—

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

*Estimated acquisition cost (EAC)* means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

*Innovator multiple source drug* means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA).

*Lagged price concession* means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

*Manufacturer* means any entity that possesses legal title to the NDC for a covered drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) With respect to authorized generic products, the term “manufacturer” will also include the original holder of the NDA.

(4) With respect to drugs subject to private labeling arrangements, the term “manufacturer” will also include the entity that does not possess legal title to the NDC.

*National drug code (NDC)* means the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in this part as being without respect to package size (that is, the 9-digit numerical code).

*National rebate agreement* means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a

manufacturer to implement section 1927 of the Act.

*Nominal price* means a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed.

*Noninnovator multiple source drug* means (1) a multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed under an abbreviated NDA or an abbreviated antibiotic drug application, or (3) a drug that entered the market before 1962 that was not originally marketed under an original NDA.

*Rebate period* means a calendar quarter.

*Single source drug* means a covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application, PLA, ELA, or ADA.

*States* means the 50 States and the District of Columbia.

[72 FR 39239, July 17, 2007, as amended at 73 FR 13788, Mar. 14, 2008; 73 FR 58497, Oct. 7, 2008; 75 FR 69597, Nov. 15, 2010]

**§ 447.504 [Reserved]**

**§ 447.505 Determination of best price.**

(a) *Best price* means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.

(b) For purposes of this section, *provider* means a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section, best price for covered outpatient drugs includes the following prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly—

- (1) Prices to wholesalers;
- (2) Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs;
- (3) Prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies);
- (4) Prices available to non-profit entities;
- (5) Prices available to governmental entities within the United States;
- (6) Prices of authorized generic drugs, sold by the primary manufacturer in accordance with § 447.506(d) of this subpart;
- (7) Prices of sales directly to patients;
- (8) Prices available to mail order pharmacies;
- (9) Prices available to outpatient clinics;
- (10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements; and
- (11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity.

(d) *Prices excluded from best price.* Best price excludes:

- (1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the FSS of the GSA;

(3) Any prices provided to a designated SPAP;

(4) Any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(5) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA-PD plan under Part C of such title with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D-22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare;

(6) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer-sponsored drug discount card program;

(8) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(9) Goods provided free of charge under a manufacturer's patient assistance programs;

(10) Free goods, not contingent upon any purchase requirement;

(11) Nominal prices to certain entities as set forth in § 447.508 of this subpart;

(12) Bona fide service fees; and

(13) PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level.

(e) *Further clarification of best price.*

- (1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any

other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount as described in § 447.508 of this subpart.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

**§ 447.506 Authorized generic drugs.**

(a) *Authorized generic drug defined.* For the purposes of this subpart, an authorized generic drug means any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug.

(b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price for a single source or innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA.

**§ 447.508 Exclusion from best price of certain sales at a nominal price.**

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded

from best price when purchased by the following entities:

(1) A covered entity described in section 340B(a)(4) of the PHSA;

(2) An ICF/IID providing services as set forth in § 440.150 of this chapter; or

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(b) *Nonapplication.* This restriction shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38, U.S.C. 8126.

**§ 447.510 Requirements for manufacturers.**

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with section 1927(k)(1) of the Social Security Act.

(2) Best price, calculated in accordance with § 447.505 of this subpart;

(3) Customary prompt pay discounts, which shall be reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period; and

(4) Prices that fall within the nominal price exclusion, which shall be reported as an aggregate dollar amount and shall include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.

(2) A manufacturer must report revisions to AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.* (1) A manufacturer may report a revised base date AMP to CMS within the first four full calendar quarters following [OFR: insert publication date of the final rule].

(2) *Recalculation of base date AMP.* (i) A manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in section 1927(k)(1) of the Social Security Act.

(ii) A manufacturer may choose to recalculate base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating base date AMP.

(d) *Monthly AMP*—(1) *Definition of Monthly AMP.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP should be calculated based on section 1927(k)(1) of the Social Security Act, except the period covered should be based on monthly, as opposed to quarterly AMP sales.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due.

(4) *Exception.* A manufacturer must report revisions to monthly AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO);

(2) The manufacturer's chief financial officer (CFO);

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records

(written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

[72 FR 39239, July 17, 2007, as amended at 75 FR 69597, Nov. 15, 2010]

#### § 447.512 Drugs: Aggregate upper limits of payment.

(a) [Reserved]

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established must not exceed, in the aggregate, payments levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established does not apply if a physician certifies in his



#### § 447.514

or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular beneficiary.

(2) The agency must decide what certification form and procedure are used.

(3) A check-off box on a form is not acceptable but a notation like “brand necessary” is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

[72 FR 39239, July 17, 2007, as amended at 75 FR 69597, Nov. 15, 2010]

#### § 447.514 [Reserved]

#### § 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

#### § 447.518 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency’s payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs are in accordance with the established upper limits.

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in § 447.512 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

#### 42 CFR Ch. IV (10–1–15 Edition)

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

[72 FR 39239, July 17, 2007, as amended at 75 FR 69597, Nov. 15, 2010]

#### § 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

#### PART 455—PROGRAM INTEGRITY: MEDICAID

Sec.

455.1 Basis and scope.

455.2 Definitions.

455.3 Other applicable regulations.

#### Subpart A—Medicaid Agency Fraud Detection and Investigation Program

455.12 State plan requirement.

455.13 Methods for identification, investigation, and referral.

455.14 Preliminary investigation.

455.15 Full investigation.

455.16 Resolution of full investigation.